

US3562157 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:20:26

All time stamps listed in this document are displayed in GMT

US3562157

Form: Participant Creation

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

Participant ID

US3562157

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

US3562157

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3562157

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	62
Age Units	YEARS
Age (Derived)	62
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	True
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3562157

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Date of Informed Consent (dd MMM yyyy) 11 SEP 2020

Month and Year of Informed Consent (derived) SEP 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

US3562157

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3562157

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Were any significant conditions reported?

Yes ☒

No ☐

US3562157

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

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

US3562157

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

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

US3562157

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3562157

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

Condition	POST MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3562157

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3562157

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

Condition	FOLIC ACID DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3562157

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN JUN 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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3562157

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3562157

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

Condition	RIGHT LOWER ABDOMEN PAIN
Start date (dd MMM yyyy)	UN JAN 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3562157

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

Condition	PELVIC PAIN
Start date (dd MMM yyyy)	UN DEC 2019
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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3562157

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

Condition	POST MENOPAUSE SYNDROME
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3562157

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

Condition	FIBROID UTERUS
Start date (dd MMM yyyy)	27 AUG 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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3562157

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 10 Mar 2021 16:38:50

Generated On: 10 Jun 2021 08:20:26

Condition	BENIGN BILATERAL OVARIAN COMPLEX CYST
Start date (dd MMM yyyy)	27 AUG 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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3562157

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:58
Height (xxx.x)	63 in
Weight (xxx.x)	126 lb
BMI (xxx.x)	22.36657 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)	

US3562157

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3562157

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Date of assessment (dd MMM yyyy) 11 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2008

Date of last menstruation unknown False

US3562157

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

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

US3562157

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

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	

US3562157

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 113528

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Height	ND - Not Done
Weight	ND - Not Done

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

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)	11 SEP 2020
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:58
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

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)	11 SEP 2020
Time of assessment (00:00-23:59)	17:32 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 17:32
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3562157

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

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.

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 16:54 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 16:54

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

US3562157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	16:12 (24 HR)
Collection date and time (derived)	11 SEP 2020 16:12

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:10	11 SEP 2020 16:10
Nasopharyngeal Swab 2	No		

US3562157

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 11 SEP 2020 17:35

PC Open Date & Time 11 SEP 2020 17:14

PC Close Date & Time 11 SEP 2020 19:44

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	11 SEP 2020 21:44
PC Open Date & Time	11 SEP 2020 20:39
PC Close Date & Time	12 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

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

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

PC Time Stamp	12 SEP 2020 20:43
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

13 SEP 2020 21:05

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

98.0 °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

14 SEP 2020 20:30

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 20:11

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

97.9 °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

16 SEP 2020 20:47

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 19:16

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

11 SEP 2020 17:35

PC Open Date & Time

11 SEP 2020 17:14

PC Close Date & Time

11 SEP 2020 19:44

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

11 SEP 2020 21:45

PC Open Date & Time

11 SEP 2020 20:39

PC Close Date & Time

12 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

12 SEP 2020 20:44

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

13 SEP 2020 21:05

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

14 SEP 2020 20:31

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

15 SEP 2020 20:12

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

16 SEP 2020 20:48

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

17 SEP 2020 19:16

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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 ☐

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 17:36
PC Open Date & Time	11 SEP 2020 17:14
PC Close Date & Time	11 SEP 2020 19:44

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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 ☐

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 21:45
PC Open Date & Time	11 SEP 2020 20:39
PC Close Date & Time	12 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

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)

55 of 1723

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	12 SEP 2020 20:45
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

EAB) (1725)

57 of 1723

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	13 SEP 2020 21:06
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

59 of 1723

EAB) (1725)

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	14 SEP 2020 20:31
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

EAB) (1725)

61 of 1723

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	15 SEP 2020 20:12
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

63 of 1723

EAB) (1725)

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	16 SEP 2020 20:49
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

EAB) (1725)

65 of 1723

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	17 SEP 2020 19:17
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3562157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562157

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562157

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3562157

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	16:02 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 16:02
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	17:18 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 17:18
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3562157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 OCT 2020

What was the treatment time? (00:00-23:59) 16:45 (24 HR)

Treatment Date and Time (derived) 14 OCT 2020 16:45

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

US3562157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	14 OCT 2020
Collection time (00:00-23:59)	16:10 (24 HR)
Collection date and time (derived)	14 OCT 2020 16:10

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Collection date (dd MMM yyyy)			14 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:27	14 OCT 2020 16:27
Nasopharyngeal Swab 2	No		

US3562157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

98.3 °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

14 OCT 2020 17:20

PC Open Date & Time

14 OCT 2020 17:05

PC Close Date & Time

14 OCT 2020 19:35

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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 98.6 °F

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

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

PC Time Stamp	14 OCT 2020 21:30
PC Open Date & Time	14 OCT 2020 20:30
PC Close Date & Time	15 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

98.8 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

15 OCT 2020 21:17

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 21:43

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 21:51

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

97.9 °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

18 OCT 2020 19:32

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 22:00

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 21:47

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 17:20

PC Open Date & Time

14 OCT 2020 17:05

PC Close Date & Time

14 OCT 2020 19:35

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 21:31

PC Open Date & Time

14 OCT 2020 20:30

PC Close Date & Time

15 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

125

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☒

No ☐

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

25

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 21:21

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 21:44

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 21:52

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 19:32

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 22:00

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 21:48

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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 ☐

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 17:21
PC Open Date & Time	14 OCT 2020 17:05
PC Close Date & Time	14 OCT 2020 19:35

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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 ☐

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 21:32
PC Open Date & Time	14 OCT 2020 20:30
PC Close Date & Time	15 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

101 of 1723

EAB) (1725)

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	15 OCT 2020 21:22
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

103 of 1723

EAB) (1725)

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	16 OCT 2020 21:45
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

105 of 1723

EAB) (1725)

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	17 OCT 2020 21:52
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

107 of 1723

EAB) (1725)

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	18 OCT 2020 19:33
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

109 of 1723

EAB) (1725)

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	19 OCT 2020 22:01
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

EAB) (1725)

111 of 1723

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

Yes ☐	
PC Time stamp	20 OCT 2020 21:48
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3562157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562157

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562157

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562157

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	13:03 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 13:03
Temperature (xxx.x)	98.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3562157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	11 NOV 2020

Collection time (00:00-23:59)	13:10 (24 HR)

Collection date and time (derived)	11 NOV 2020 13:10

US3562157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:58:04

Generated On: 10 Jun 2021 08:20:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

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 ☐
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):	
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 ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	11 NOV 2020 13:12:17
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

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°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 ☐

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 09:14:05
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
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):	
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 ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 18:07:12
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3562157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 20:00:39

Generated On: 10 Jun 2021 08:20:26

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

US3562157

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 20:00:39

Generated On: 10 Jun 2021 08:20:26

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3562157

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

AEID	USA-US071-2020-MRNA-1273-P30 1000002
Adverse event	PELVIC CANCER
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)	04 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

132 of 1723

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	False
Concomitant Procedure	True
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	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

CT PERFORMED ON 05NOV2020
- IMAGED PORTIONS OF THE
LOWEST THORAX
DEMONSTRATE INNER
BIBASILLER ATELECTESIS,
CYTOLOGY REPORT- 3
DIMENSIONAL CLUSTER OF
PLEOMORPHIC CELLS. THE
FOLLOWING TEST ARE
PERFORMED AND SUPPORT
THE DIAGNOSIS
IMMUNOHISTOCHEMISTRY
SHOWS THE CELLS OF
INTEREST TO BE POSITIVE FOR
MOC31, CK20;CDX2,SATB2 AND
CK7. NEGATIVE FOR WT1,
ER,P53, VIMENTIN

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

AEID	USA-US071-2020-MRNA-1273-P30 1000002
Adverse event	COLORECTAL CANCER
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)	04 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

135 of 1723

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	False
Concomitant Procedure	True
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	PATIENT SELF REPORTED THAT 8 SESSIONS OF CHEMOTHERAPY WERE STARTED ON 23NOV2020, CT AND CYTOLOGY REPORT WAS ADDED UNDER AE # 1
Serious Adverse Event Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	

136 of 1723

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

AEID	
Adverse event	SHINGLES
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)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	07 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

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

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

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

PRODUCTION RELEASE (v12.003

140 of 1723

EAB) (1725)

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

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

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

AEID

Adverse event

BIBASILAR ATELECTASIS.

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)

05 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

142 of 1723

EAB) (1725)

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 24 Mar 2021 18:36:40

Generated On: 10 Jun 2021 08:20:26

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

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 14:58:03

Generated On: 10 Jun 2021 08:20:26

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

Yes ☒

No ☐

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

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication FOSAMAX

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 70

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

145 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☒
	804	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 4000

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)

147 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication FOLIC ACID

Prophylaxis Yes ☐
No ☒

Indication FOLIC ACID DEFICIENCY

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

149 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication MELTONIN

Prophylaxis Yes ☐
No ☒

Indication INSOMINIA

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)

151 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication LEXAPRO

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

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)

153 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication ESTRADIOL CREAM

Prophylaxis Yes ☐
No ☒

Indication POST MENOPAUSE SYNDROME

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

2 TIMES A WEEK

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

155 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication SUMATRIPTAN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

157 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 325

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)

159 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	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)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 12 SEP 2020		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 650

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)

161 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	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)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication ACYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication SHINGLES

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

FIVE TIMES A DAY

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

163 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	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)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication PROGESTERONE CAPS

Prophylaxis Yes ☐
No ☒

Indication POST MENOPAUSE SYNDROME

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

165 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication LIDOCAINE 2% CREAM

Prophylaxis Yes ☐
No ☒

Indication SHINGLES

Dose per administration 1

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

If dose unit is Other, specify APPLICATOR

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)

167 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	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)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		05 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

169 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	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)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		30 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

Name of Medication VITAMIN B12

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

171 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Feb 2021 14:58:02

Generated On: 10 Jun 2021 08:20:26

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 14:58:03

Generated On: 10 Jun 2021 08:20:26

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Mar 2021 18:36:41

Generated On: 10 Jun 2021 08:20:26

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 NOV 2020	CT OF ABDOMEN WITH CONTRAST	Adverse Event	
04 NOV 2020	PERITONEAL WASH	Adverse Event	
04 NOV 2020	DIAGNOSTIC LAPAROSCOPY	Adverse Event	
06 NOV 2020	COLORECTAL CYTOLOGY	Adverse Event	

US3562157

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 10 Mar 2021 16:38:47

Generated On: 10 Jun 2021 08:20:26

Date of study discontinuation/completion (dd MMM yyyy) 2 DEC 2020

Reason for discontinuation

AE (specify)	☐
SAE (specify)	☒
Complete	☐
Death	☐
Lost To Follow-up	☐
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Other	☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SAE # 2

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	☐

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 24 Mar 2021 18:36:41

Generated On: 10 Jun 2021 08:20:26

SAEID	USA-US071-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	8

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Mar 2021 18:36:41

Generated On: 10 Jun 2021 08:20:26

SAEID	USA-US071-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	06/NOV/2020 22:58
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

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Mar 2021 18:36:41

Generated On: 10 Jun 2021 08:20:26

SAEID	USA-US071-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	10/NOV/2020 14:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Mar 2021 18:36:41

Generated On: 10 Jun 2021 08:20:26

SAEID	USA-US071-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	11/NOV/2020 19:56
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

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Mar 2021 18:36:41

Generated On: 10 Jun 2021 08:20:26

SAEID	USA-US071-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	12/NOV/2020 15:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 24 Mar 2021 18:36:41

Generated On: 10 Jun 2021 08:20:26

SAEID	USA-US071-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	03/FEB/2021 10:39
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

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 24 Mar 2021 18:36:41

Generated On: 10 Jun 2021 08:20:26

SAEID	USA-US071-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	04/FEB/2021 14:49
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

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 24 Mar 2021 18:36:41

Generated On: 10 Jun 2021 08:20:26

SAEID	USA-US071-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	10/FEB/2021 10:35
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

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 24 Mar 2021 18:36:41

Generated On: 10 Jun 2021 08:20:26

SAEID	USA-US071-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	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)	8
Date of submission (Pre-filled from custom function)	18/MAR/2021 10:18
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

US3562157 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3562157

Form: Participant Creation

Generated On: 10 Jun 2021 08:20:26

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:45:50
User entered 'US3562157'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 22:34:57

US3562157

Form: Participant Creation

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:18
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:47:50

US3562157

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:18
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 22:35:02

US3562157

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:18
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:47:50

US3562157

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'SCRN'	System	13 Sep 2020 21:47:50

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered (b) (6) 1957'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 22:35:06

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '62'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'YEARS'	System	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '62'	System	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered 'Female (F)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered 'I'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered 'I'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:26

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered '11 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Sep 2020'	System	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2020'	System	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:26

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered 'No (N)'	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 22:35:02

US3562157

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:54:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:20:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:54:45
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:47:57

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
Data point term sent to Coder	System	13 Sep 2020 21:49:07
User entered 'osteoporosis'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2015'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Jan 2015'	System	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2015'	System	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
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)	05 Oct 2020 15:54:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 15:54:20
Data point term sent to Coder	System	13 Sep 2020 21:49:08
User entered 'vitamin d deficiency'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2015'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Jan 2015'	System	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2015'	System	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
Data point term sent to Coder	System	13 Sep 2020 21:49:07
User entered 'insomnia'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2008'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Jan 2008'	System	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2008'	System	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
Data point term sent to Coder	System	13 Sep 2020 21:49:07
User entered 'post menopause'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2008'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Jan 2008'	System	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2008'	System	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:20:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 21:51:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 21:51:39
Data point term sent to Coder	System	13 Sep 2020 21:50:11
User entered 'migraine headaches'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2008'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Jan 2008'	System	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:20:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2008'	System	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:20:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Folate deficiency, LLT: Folic acid deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:51:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:51:39
Data point term sent to Coder	System	13 Sep 2020 21:50:11
User entered 'folic acid deficiency'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2019'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:20:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Jan 2019'	System	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2019'	System	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:20:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 16:06:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 16:06:51
Data point term sent to Coder	System	17 Nov 2020 15:36:03
User entered 'hypercholesterolemia'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un Jun 2020'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Jun 2020'	System	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2020'	System	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:20:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 15:36:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 15:36:53
Data point term sent to Coder	System	17 Nov 2020 15:36:03
User entered 'anxiety'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2018'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Jan 2018'	System	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2018'	System	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:20:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain lower, LLT: Right lower quadrant pain - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 16:11:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 16:11:52
Data point term sent to Coder	System	17 Nov 2020 15:36:04
User entered 'right lower abdomen pain'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un Jan 2019'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Jan 2019'	System	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2019'	System	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:20:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Reproductive tract disorders NEC, HLT: Reproductive tract signs and symptoms NEC, PT: Pelvic pain, LLT: Pelvic pain - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 15:37:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 15:37:48
Data point term sent to Coder	System	17 Nov 2020 15:37:05
User entered 'pelvic pain'	Dhwani Shah (b) (4)	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un Dec 2019'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:20:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4) (b) (4)	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Dec 2019'	System	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2019'	System	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:20:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menopause related conditions, HLT: Menopausal effects NEC, PT: Menopausal symptoms, LLT: Postmenopausal syndrome - version MedDRA\23.0.	Coder Import (b) (4)	12 Feb 2021 09:29:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Feb 2021 09:29:43
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:23:45
Data point term sent to Coder	System	01 Feb 2021 14:03:26
User entered 'post menopause syndrome'	Dhwani Shah (b) (4)	01 Feb 2021 14:02:40

US3562157

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:23:47
User entered 'un UNK 2010'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 14:02:40

US3562157

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:23:49
User entered '0'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 14:02:40

US3562157

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:23:51
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 14:02:40

US3562157

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:23:53
User entered empty.	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 14:02:40

US3562157

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:23:55
User entered '0'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 14:02:40

US3562157

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Jan 2010'	System	01 Feb 2021 14:02:40

US3562157

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:20:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2010'	System	01 Feb 2021 14:02:40

US3562157

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	01 Feb 2021 14:02:40

US3562157

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	01 Feb 2021 14:02:40

US3562157

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:20:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:21:57
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroid - version MedDRA\23.0.	Coder Import (b) (4)	03 Feb 2021 20:29:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Feb 2021 20:29:28
Data point term sent to Coder	System	03 Feb 2021 20:28:56
User entered 'fibroid uterus' reason for change: Data Entry Error	Dhwani Shah (b) (4)	03 Feb 2021 20:28:45
Data point term sent to Coder	System	03 Feb 2021 20:27:53
User entered 'post menopause syndrome'	Dhwani Shah (b) (4)	03 Feb 2021 20:27:49

US3562157

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:22:00
User entered '27 Aug 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	03 Feb 2021 20:28:45
User entered 'un UNK 2010'	(b) (4) Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:27:49

US3562157

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:20:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:22:02
User entered '0'	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:27:49

US3562157

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:22:04
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:27:49

US3562157

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:22:06
User entered empty.	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:27:49

US3562157

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:22:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:27:49

US3562157

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Aug 2020'	System	03 Feb 2021 20:28:45
User entered 'Jan 2010'	System	03 Feb 2021 20:27:49

US3562157

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2020'	System	03 Feb 2021 20:28:45
User entered '2010'	System	03 Feb 2021 20:27:49

US3562157

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	03 Feb 2021 20:27:49

US3562157

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	03 Feb 2021 20:27:49

US3562157

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:20:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User coded data point as SOC: Reproductive system and breast disorders, HLG: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Benign ovarian cyst - version MedDRA\23.0.	Coder Import (b) (4)	16 Mar 2021 13:31:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Mar 2021 13:31:50
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
User closed query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:46:22
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:22:20
Data point term sent to Coder	System	25 Feb 2021 18:56:33
Query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4)	25 Feb 2021 18:55:52
Coding entries removed.	Dhwani Shah (b) (4)	25 Feb 2021 18:55:44
User entered 'BENIGN BILATERAL OVARIAN COMPLEX CYST' reason for change: Data Entry Error	Dhwani Shah (b) (4)	25 Feb 2021 18:55:44
User opened query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:00:31

US3562157

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:20:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Complex ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 09:26:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 09:26:43
Data point term sent to Coder	System	03 Feb 2021 20:29:56
User entered 'ovarian complex cyst'	Dhwani Shah (b) (4)	03 Feb 2021 20:29:04

US3562157

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:22:22
User entered '27 Aug 2020'	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:29:04

US3562157

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:20:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:22:25
User entered '0'	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:29:04

US3562157

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:20:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:22:31
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:29:04

US3562157

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:22:33
User entered empty.	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:29:04

US3562157

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:20:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:22:35
User entered '0'	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:29:04

US3562157

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'Aug 2020'	System	03 Feb 2021 20:29:04

US3562157

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2020'	System	03 Feb 2021 20:29:04

US3562157

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	03 Feb 2021 20:29:04

US3562157

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	03 Feb 2021 20:29:04

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered '11 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 22:46:34
User closed query 'Please confirm time. Per source, 15:58 is recorded. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:46:28
Query 'Please confirm time. Per source, 15:58 is recorded. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	18 Nov 2020 22:23:49
DataPoint Un-verified.	(b) (4)	
	Dhwani Shah (b) (4)	18 Nov 2020 22:23:42
User entered '15:58' reason for change: Data Entry Error	Dhwani Shah (b) (4)	18 Nov 2020 22:23:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User opened query 'Please confirm time. Per source, 15:58 is recorded. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:46:57
User entered '16:02'	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
	(b) (4)	

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '11 Sep 2020 15:58'	System	18 Nov 2020 22:23:42
User entered '11 Sep 2020 16:02'	System	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered '63' in	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
DataPoint set to visible.	(b) (4) System	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered '126' lb	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
DataPoint set to visible.	(b) (4) System	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '22.36657'	System	20 Oct 2020 14:01:10
DataPoint set to visible.	System	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'kg/m2'	System	20 Oct 2020 14:01:10
DataPoint set to visible.	System	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'bpm'	System	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'breaths/min'	System	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:50:05

US3562157

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered '11 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:50:05

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:20:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered '11 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:50:41

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:20:26

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:50:41

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:20:26

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:50:41

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:20:26

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:50:41

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:20:26

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:50:41

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:20:26

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:50:41

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:20:26

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered 'un UNK 2008'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:50:41

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:20:26

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:50:41

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User entered '0'	(b) (4) Dhwani Shah (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'I'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User entered '0'	(b) (4) Dhwani Shah (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:54:45
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:56

US3562157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:54:45
User entered '11 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:56

US3562157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:54:45
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:56

US3562157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'VISIT1'	System	13 Sep 2020 21:51:56

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 23:29:15

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered '113528'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 23:29:15

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 23:29:15

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:26

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)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:43

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:26

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)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:43

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:43

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:43

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:43

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:26

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User closed query 'Please complete Vital Sign - Dosing eCRF (next eCRF). ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:47:00
Query 'Please complete Vital Sign - Dosing eCRF (next eCRF). ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:28:08
User opened query 'Please complete Vital Sign - Dosing eCRF (next eCRF). ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:56:56
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 16:47:41
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:04:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:04:37

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:56:56
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:56:58
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:56:56
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:56:58
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:56:59
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:02
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:26:30
User entered '11 Sep 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	18 Nov 2020 22:26:30
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:25:21
User entered '18 Nov 2020'	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:04
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:26:30
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:25:21
User entered '15:58'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '11 Sep 2020 15:58'	System	18 Nov 2020 22:26:30
User entered '18 Nov 2020 15:58'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 18:49:24
User closed query 'Please confirm response. Per source, 98.0 is documented. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:49:21
Query 'Please confirm response. Per source, 98.0 is documented. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	02 Feb 2021 19:23:44
User entered '98.0' F reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:57:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:57:06
User opened query 'Please confirm response. Per source, 98.0 is documented. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:56:53
User entered '98.3' F	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:42
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:44
User entered empty.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:50
User entered '66'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'bpm'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 18:48:15
User closed query 'Please confirm response. Source has 14 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:48:13
Query 'Please confirm response. Source has 14 captured. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	02 Feb 2021 19:23:50
User entered '14' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	02 Feb 2021 17:54:54
User opened query 'Please confirm response. Source has 14 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:58:50
User entered '16'	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'breaths/min'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 18:48:21
User closed query 'Please confirm response. Source has 120 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:48:18
Query 'Please confirm response. Source has 120 captured. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	02 Feb 2021 19:23:56
User entered '120' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	02 Feb 2021 17:54:54
User opened query 'Please confirm response. Source has 120 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:59:15
User entered '122'	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 18:48:26
User closed query 'Please confirm response. Source has 78 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:48:24
Query 'Please confirm response. Source has 78 captured. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	02 Feb 2021 19:24:02
User entered '78' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	02 Feb 2021 17:54:54
User opened query 'Please confirm response. Source has 78 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:59:44
User entered '74'	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:56:56
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:56:58
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:00:06
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:00:08
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:26:30
User entered '11 Sep 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	18 Nov 2020 22:26:30
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:25:21
User entered '18 Nov 2020'	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:00:15
User entered '17:32'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '11 Sep 2020 17:32'	System	18 Nov 2020 22:26:30
User entered '18 Nov 2020 17:32'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 18:48:40
User closed query 'Please confirm response. Source has 98.0 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:48:38
Query 'Please confirm response. Source has 98.0 captured. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	02 Feb 2021 19:24:51
User entered '98.0' F reason for change: Data Entry Error	(b) (4)	
User opened query 'Please confirm response. Source has 98.0 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:00:36
User entered '98.9' F	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:00:39
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:00:41
User entered empty.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 18:48:46
User closed query 'Please confirm response. Source has 59 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:48:43
Query 'Please confirm response. Source has 59 captured. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	02 Feb 2021 19:24:47
User entered '59' reason for change: Data Entry Error	(b) (4)	
	(b) (4)	02 Feb 2021 17:55:19
User opened query 'Please confirm response. Source has 59 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:01:07
User entered '72'	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'bpm'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 18:48:52
User closed query 'Please confirm response. Source has 16 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:48:50
Query 'Please confirm response. Source has 16 captured. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	02 Feb 2021 19:24:42
User entered '16' reason for change: Data Entry Error	(b) (4)	
User opened query 'Please confirm response. Source has 16 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:04:23
User entered '14'	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'breaths/min'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 18:48:57
User closed query 'Please confirm response. Source has 130 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:48:55
Query 'Please confirm response. Source has 130 captured. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	02 Feb 2021 19:24:34
User entered '130' reason for change: Data Entry Error	(b) (4)	
User opened query 'Please confirm response. Source has 130 captured. Please update as applicable. ' (Site from CRA).	Dhwani Shah (b) (4)	02 Feb 2021 17:55:19
	(b) (4), (b) (6)	
User entered '105'	(b) (4), (b) (6)	02 Feb 2021 17:04:48
	Dhwani Shah (b) (4)	
	(b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Feb 2021 18:49:03
User closed query 'Please confirm response. Source has 79 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:49:00
Query 'Please confirm response. Source has 79 captured. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	02 Feb 2021 19:24:38
User entered '79' reason for change: Data Entry Error	(b) (4)	
User opened query 'Please confirm response. Source has 79 captured. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:05:14
User entered '71'	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:07
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:03

US3562157

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:07
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:03

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

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)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'MRNA-1273 OR PLACEBO'	System	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered '11 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered '16:54'	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '11 Sep 2020 16:54'	System	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered 'ONCE'	System	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'INTRAMUSCULAR'	System	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:20

US3562157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:16
User entered '11 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:20

US3562157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:16
User entered '16:12'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:20

US3562157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '11 Sep 2020 16:12'	System	13 Sep 2020 21:52:20

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:20:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:32
User entered '11 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:32
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:32
User entered '16:10'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '11 Sep 2020 16:10'	System	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:32
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:32
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:41
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:47

US3562157

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	13 Sep 2020 21:52:47

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:33:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd789eac3-a84b-49db-808b-ff4d2efe19f8' User entered 'Yes (Y)'	System	12 Sep 2020 00:35:07
	System	12 Sep 2020 00:35:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:34:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd789eac3-a84b-49db-808b-ff4d2efe19f8' User entered '98.0'	System	12 Sep 2020 00:35:07
	System	12 Sep 2020 00:35:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:34:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd789eac3-a84b-49db-808b-ff4d2efe19f8'	System	12 Sep 2020 00:35:07
User entered 'No (N)'	System	12 Sep 2020 00:35:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:01', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd789eac3-a84b-49db-808b-ff4d2efe19f8'	System	12 Sep 2020 00:35:07
User entered '11 Sep 2020 17:35'	System	12 Sep 2020 00:35:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '11 Sep 2020 17:14'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '11 Sep 2020 19:44'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:43:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '59ffcf7-6ba8-4fb9-a8e8-24edfb5f4ecd'	System	12 Sep 2020 04:44:15
User entered 'Yes (Y)'	System	12 Sep 2020 04:44:15

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:43:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '59ffcf7-6ba8-4fb9-a8e8-24edfb5f4ecd' User entered '98.0'	System	12 Sep 2020 04:44:15
	System	12 Sep 2020 04:44:15

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:43:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '59ffcf7-6ba8-4fb9-a8e8-24edfb5f4ecd'	System	12 Sep 2020 04:44:15
User entered 'No (N)'	System	12 Sep 2020 04:44:15

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:44:13', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '59ffcf7-6ba8-4fb9-a8e8-24edfb5f4ecd'	System	12 Sep 2020 04:44:15
User entered '11 Sep 2020 21:44'	System	12 Sep 2020 04:44:15

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '11 Sep 2020 20:39'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '12 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 2'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:41:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51' User entered 'Yes (Y)'	System	13 Sep 2020 03:43:57
	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:42:07', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51' User entered '98.0'	System	13 Sep 2020 03:43:57
	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51'	System	13 Sep 2020 03:43:57
User entered 'Yes (Y)'	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'sw pt and added con med line 8' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 05:36:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Dhwani Shah (b) (4)	26 Sep 2020 17:43:30
and added con med line 8' (Site from System).	(b) (4)	
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Sep 2020 03:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:42:46', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51'	System	13 Sep 2020 03:43:57
User entered '1'	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:42:46', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51' User entered '0'	System	13 Sep 2020 03:43:57
	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:21', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51' User entered '12 Sep 2020 20:43'	System	13 Sep 2020 03:43:57
	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '12 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 3'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:04:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'b3ef43da-439e-49f5-a70c-aafb685c9977' User entered 'Yes (Y)'	System	14 Sep 2020 04:05:14
	System	14 Sep 2020 04:05:14

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:04:58', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'b3ef43da-439e-49f5-a70c-aafb685c9977' User entered '98.0'	System	14 Sep 2020 04:05:14
	System	14 Sep 2020 04:05:14

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'b3ef43da-439e-49f5-a70c-aafb685c9977'	System	14 Sep 2020 04:05:14
User entered 'No (N)'	System	14 Sep 2020 04:05:14

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'b3ef43da-439e-49f5-a70c-aafb685c9977'	System	14 Sep 2020 04:05:14
User entered '13 Sep 2020 21:05'	System	14 Sep 2020 04:05:14

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 4'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:10', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5ef55c79-0dc8-4fd5-8e24-74c4bf49ca98' User entered 'Yes (Y)'	System	15 Sep 2020 03:30:30
	System	15 Sep 2020 03:30:30

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5ef55c79-0dc8-4fd5-8e24-74c4bf49ca98' User entered '98.0'	System	15 Sep 2020 03:30:30
	System	15 Sep 2020 03:30:30

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:21', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5ef55c79-0dc8-4fd5-8e24-74c4bf49ca98'	System	15 Sep 2020 03:30:30
User entered 'No (N)'	System	15 Sep 2020 03:30:30

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5ef55c79-0dc8-4fd5-8e24-74c4bf49ca98' User entered '14 Sep 2020 20:30'	System	15 Sep 2020 03:30:30
	System	15 Sep 2020 03:30:30

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 5'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5631e5d0-d83c-4d48-b7eb-9cf4a2e13ce6' User entered 'Yes (Y)'	System	16 Sep 2020 03:11:51
	System	16 Sep 2020 03:11:51

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:38', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5631e5d0-d83c-4d48-b7eb-9cf4a2e13ce6' User entered '97.6'	System	16 Sep 2020 03:11:51
	System	16 Sep 2020 03:11:51

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5631e5d0-d83c-4d48-b7eb-9cf4a2e13ce6' User entered 'No (N)'	System	16 Sep 2020 03:11:51
	System	16 Sep 2020 03:11:51

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5631e5d0-d83c-4d48-b7eb-9cf4a2e13ce6' User entered '15 Sep 2020 20:11'	System	16 Sep 2020 03:11:51
	System	16 Sep 2020 03:11:51

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 6'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:47:31', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c4ace321-0203-4dee-9721-7292534efb7e' User entered 'Yes (Y)'	System	17 Sep 2020 03:47:54
	System	17 Sep 2020 03:47:54

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:47:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c4ace321-0203-4dee-9721-7292534efb7e' User entered '97.9'	System	17 Sep 2020 03:47:54
	System	17 Sep 2020 03:47:54

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:47:45', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c4ace321-0203-4dee-9721-7292534efb7e' User entered 'No (N)'	System	17 Sep 2020 03:47:54
	System	17 Sep 2020 03:47:54

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:47:50', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c4ace321-0203-4dee-9721-7292534efb7e' User entered '16 Sep 2020 20:47'	System	17 Sep 2020 03:47:54
	System	17 Sep 2020 03:47:54

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 7'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4080a848-69f5-490a-8d40-67a80925dc19' User entered 'Yes (Y)'	System	18 Sep 2020 02:16:29
	System	18 Sep 2020 02:16:29

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4080a848-69f5-490a-8d40-67a80925dc19' User entered '98.2'	System	18 Sep 2020 02:16:29
	System	18 Sep 2020 02:16:29

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4080a848-69f5-490a-8d40-67a80925dc19' User entered 'No (N)'	System	18 Sep 2020 02:16:29
	System	18 Sep 2020 02:16:29

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:26', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4080a848-69f5-490a-8d40-67a80925dc19' User entered '17 Sep 2020 19:16'	System	18 Sep 2020 02:16:29
	System	18 Sep 2020 02:16:29

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8a6c76e5-0e5e-4212-8ae9-2dc5f2221e08'	System	12 Sep 2020 00:35:50
User entered 'None (1)'	System	12 Sep 2020 00:35:50

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:23', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8a6c76e5-0e5e-4212-8ae9-2dc5f2221e08' User entered 'No (N)'	System	12 Sep 2020 00:35:50
	System	12 Sep 2020 00:35:50

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8a6c76e5-0e5e-4212-8ae9-2dc5f2221e08' User entered 'No (N)'	System	12 Sep 2020 00:35:50
	System	12 Sep 2020 00:35:50

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:41', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8a6c76e5-0e5e-4212-8ae9-2dc5f2221e08'	System	12 Sep 2020 00:35:50
User entered 'None (1)'	System	12 Sep 2020 00:35:50

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8a6c76e5-0e5e-4212-8ae9-2dc5f2221e08' User entered '11 Sep 2020 17:35'	System	12 Sep 2020 00:35:50
	System	12 Sep 2020 00:35:50

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '11 Sep 2020 17:14'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '11 Sep 2020 19:44'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:44:31', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '13289dd5-d80a-4cf8-bf26-e152f427ef02'	System	12 Sep 2020 04:45:11
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 04:45:11

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:44:37', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '13289dd5-d80a-4cf8-bf26-e152f427ef02'	System	12 Sep 2020 04:45:11
User entered 'No (N)'	System	12 Sep 2020 04:45:11

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:44:47', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '13289dd5-d80a-4cf8-bf26-e152f427ef02'	System	12 Sep 2020 04:45:11
User entered 'No (N)'	System	12 Sep 2020 04:45:11

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:44:54', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '13289dd5-d80a-4cf8-bf26-e152f427ef02'	System	12 Sep 2020 04:45:11
User entered 'None (1)'	System	12 Sep 2020 04:45:11

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:03', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '13289dd5-d80a-4cf8-bf26-e152f427ef02'	System	12 Sep 2020 04:45:11
User entered '11 Sep 2020 21:45'	System	12 Sep 2020 04:45:11

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '11 Sep 2020 20:39'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '12 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 2'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:34', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '077ec4d8-2602-4717-926c-8270b560b26f' User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 03:44:18
	System	13 Sep 2020 03:44:18

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:39', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '077ec4d8-2602-4717-926c-8270b560b26f' User entered 'No (N)'	System	13 Sep 2020 03:44:18
	System	13 Sep 2020 03:44:18

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:51', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '077ec4d8-2602-4717-926c-8270b560b26f' User entered 'No (N)'	System	13 Sep 2020 03:44:18
	System	13 Sep 2020 03:44:18

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '077ec4d8-2602-4717-926c-8270b560b26f' User entered 'None (1)'	System	13 Sep 2020 03:44:18
	System	13 Sep 2020 03:44:18

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:44:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '077ec4d8-2602-4717-926c-8270b560b26f' User entered '12 Sep 2020 20:44'	System	13 Sep 2020 03:44:18
	System	13 Sep 2020 03:44:18

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '12 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 3'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '04f1d3a4-2953-4ba7-8840-5839444f9e74'	System	14 Sep 2020 04:05:57
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 04:05:57

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '04f1d3a4-2953-4ba7-8840-5839444f9e74' User entered 'No (N)'	System	14 Sep 2020 04:05:57
	System	14 Sep 2020 04:05:57

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:37', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '04f1d3a4-2953-4ba7-8840-5839444f9e74' User entered 'No (N)'	System	14 Sep 2020 04:05:57
	System	14 Sep 2020 04:05:57

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '04f1d3a4-2953-4ba7-8840-5839444f9e74'	System	14 Sep 2020 04:05:57
User entered 'None (1)'	System	14 Sep 2020 04:05:57

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:54', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '04f1d3a4-2953-4ba7-8840-5839444f9e74' User entered '13 Sep 2020 21:05'	System	14 Sep 2020 04:05:57
	System	14 Sep 2020 04:05:57

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 4'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6b84dd05-cde4-47d4-9768-131d5766043c'	System	15 Sep 2020 03:31:10
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 03:31:10

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:46', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6b84dd05-cde4-47d4-9768-131d5766043c' User entered 'No (N)'	System	15 Sep 2020 03:31:10
	System	15 Sep 2020 03:31:10

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6b84dd05-cde4-47d4-9768-131d5766043c' User entered 'No (N)'	System	15 Sep 2020 03:31:10
	System	15 Sep 2020 03:31:10

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:58', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6b84dd05-cde4-47d4-9768-131d5766043c'	System	15 Sep 2020 03:31:10
User entered 'None (1)'	System	15 Sep 2020 03:31:10

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:07', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6b84dd05-cde4-47d4-9768-131d5766043c' User entered '14 Sep 2020 20:31'	System	15 Sep 2020 03:31:10
	System	15 Sep 2020 03:31:10

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 5'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:54', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5f721a77-369e-414a-ad55-effd1ec0ff50'	System	16 Sep 2020 03:12:24
User entered 'None (1)'	System	16 Sep 2020 03:12:24

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5f721a77-369e-414a-ad55-effd1ec0ff50' User entered 'No (N)'	System	16 Sep 2020 03:12:24
	System	16 Sep 2020 03:12:24

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5f721a77-369e-414a-ad55-effd1ec0ff50'	System	16 Sep 2020 03:12:24
User entered 'No (N)'	System	16 Sep 2020 03:12:24

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:10', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5f721a77-369e-414a-ad55-effd1ec0ff50' User entered 'None (1)'	System	16 Sep 2020 03:12:24
	System	16 Sep 2020 03:12:24

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5f721a77-369e-414a-ad55-effd1ec0ff50' User entered '15 Sep 2020 20:12'	System	16 Sep 2020 03:12:24
	System	16 Sep 2020 03:12:24

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 6'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:47:58', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd5049ade-f843-47c4-ad56-d004b029bb68'	System	17 Sep 2020 03:48:23
User entered 'None (1)'	System	17 Sep 2020 03:48:23

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:01', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd5049ade-f843-47c4-ad56-d004b029bb68' User entered 'No (N)'	System	17 Sep 2020 03:48:23
	System	17 Sep 2020 03:48:23

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd5049ade-f843-47c4-ad56-d004b029bb68' User entered 'No (N)'	System	17 Sep 2020 03:48:23
	System	17 Sep 2020 03:48:23

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:10', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd5049ade-f843-47c4-ad56-d004b029bb68' User entered 'None (1)'	System	17 Sep 2020 03:48:23
	System	17 Sep 2020 03:48:23

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd5049ade-f843-47c4-ad56-d004b029bb68' User entered '16 Sep 2020 20:48'	System	17 Sep 2020 03:48:23
	System	17 Sep 2020 03:48:23

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 7'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8f31b557-ead9-46ca-9b8a-ef0c23eb4a43'	System	18 Sep 2020 02:16:52
User entered 'None (1)'	System	18 Sep 2020 02:16:52

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:35', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8f31b557-ead9-46ca-9b8a-ef0c23eb4a43'	System	18 Sep 2020 02:16:52
User entered 'No (N)'	System	18 Sep 2020 02:16:52

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:38', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8f31b557-ead9-46ca-9b8a-ef0c23eb4a43'	System	18 Sep 2020 02:16:52
User entered 'No (N)'	System	18 Sep 2020 02:16:52

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8f31b557-ead9-46ca-9b8a-ef0c23eb4a43'	System	18 Sep 2020 02:16:52
User entered 'None (1)'	System	18 Sep 2020 02:16:52

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:48', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8f31b557-ead9-46ca-9b8a-ef0c23eb4a43'	System	18 Sep 2020 02:16:52
User entered '17 Sep 2020 19:16'	System	18 Sep 2020 02:16:52

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3' User entered 'None (0)'	System	12 Sep 2020 00:36:38
	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:08', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3' User entered 'None (0)'	System	12 Sep 2020 00:36:38
	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3' User entered 'None (0)'	System	12 Sep 2020 00:36:38
	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3' User entered 'None (0)'	System	12 Sep 2020 00:36:38
	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:16', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3' User entered 'None (0)'	System	12 Sep 2020 00:36:38
	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:19', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3' User entered 'None (0)'	System	12 Sep 2020 00:36:38
	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3'	System	12 Sep 2020 00:36:38
User entered 'No (N)'	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:36', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3'	System	12 Sep 2020 00:36:38
User entered '11 Sep 2020 17:36'	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '11 Sep 2020 17:14'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '11 Sep 2020 19:44'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e' User entered 'None (0)'	System	12 Sep 2020 04:45:56
	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:16', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e' User entered 'None (0)'	System	12 Sep 2020 04:45:56
	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:21', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e' User entered 'None (0)'	System	12 Sep 2020 04:45:56
	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e' User entered 'None (0)'	System	12 Sep 2020 04:45:56
	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e' User entered 'None (0)'	System	12 Sep 2020 04:45:56
	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e' User entered 'None (0)'	System	12 Sep 2020 04:45:56
	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:41', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e' User entered 'No (N)'	System	12 Sep 2020 04:45:56
	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:55', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e' User entered '11 Sep 2020 21:45'	System	12 Sep 2020 04:45:56
	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '11 Sep 2020 20:39'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '12 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 2'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1'	System	13 Sep 2020 03:45:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:08', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1' User entered 'None (0)'	System	13 Sep 2020 03:45:52
	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:15', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1' User entered 'None (0)'	System	13 Sep 2020 03:45:52
	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1' User entered 'None (0)'	System	13 Sep 2020 03:45:52
	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:24', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1' User entered 'None (0)'	System	13 Sep 2020 03:45:52
	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1' User entered 'No interference with activity (1)'	System	13 Sep 2020 03:45:52
	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:40', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1' User entered 'No (N)'	System	13 Sep 2020 03:45:52
	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:50', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1' User entered '12 Sep 2020 20:45'	System	13 Sep 2020 03:45:52
	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '12 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 3'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647' User entered 'None (0)'	System	14 Sep 2020 04:06:39
	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:02', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647' User entered 'None (0)'	System	14 Sep 2020 04:06:39
	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647' User entered 'None (0)'	System	14 Sep 2020 04:06:39
	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647' User entered 'None (0)'	System	14 Sep 2020 04:06:39
	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:15', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647' User entered 'None (0)'	System	14 Sep 2020 04:06:39
	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647' User entered 'None (0)'	System	14 Sep 2020 04:06:39
	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:23', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647' User entered 'No (N)'	System	14 Sep 2020 04:06:39
	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:35', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647' User entered '13 Sep 2020 21:06'	System	14 Sep 2020 04:06:39
	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 4'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:13', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79' User entered 'None (0)'	System	15 Sep 2020 03:31:53
	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:16', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79' User entered 'None (0)'	System	15 Sep 2020 03:31:53
	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:19', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79' User entered 'None (0)'	System	15 Sep 2020 03:31:53
	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:22', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79' User entered 'None (0)'	System	15 Sep 2020 03:31:53
	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79' User entered 'None (0)'	System	15 Sep 2020 03:31:53
	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79' User entered 'None (0)'	System	15 Sep 2020 03:31:53
	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:36', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79' User entered 'No (N)'	System	15 Sep 2020 03:31:53
	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79' User entered '14 Sep 2020 20:31'	System	15 Sep 2020 03:31:53
	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 5'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c' User entered 'None (0)'	System	16 Sep 2020 03:13:01
	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c' User entered 'None (0)'	System	16 Sep 2020 03:13:01
	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:31', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c' User entered 'None (0)'	System	16 Sep 2020 03:13:01
	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:35', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c' User entered 'None (0)'	System	16 Sep 2020 03:13:01
	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:38', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c' User entered 'None (0)'	System	16 Sep 2020 03:13:01
	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:41', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c' User entered 'None (0)'	System	16 Sep 2020 03:13:01
	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c' User entered 'No (N)'	System	16 Sep 2020 03:13:01
	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:58', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c' User entered '15 Sep 2020 20:12'	System	16 Sep 2020 03:13:01
	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 6'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ec532b22aba' User entered 'None (0)'	System	17 Sep 2020 03:49:28
	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:36', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ee532b22aba' User entered 'None (0)'	System	17 Sep 2020 03:49:28
	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:39', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ee532b22aba' User entered 'None (0)'	System	17 Sep 2020 03:49:28
	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ee532b22aba' User entered 'None (0)'	System	17 Sep 2020 03:49:28
	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:53', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ee532b22aba' User entered 'None (0)'	System	17 Sep 2020 03:49:28
	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ee532b22aba' User entered 'None (0)'	System	17 Sep 2020 03:49:28
	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:49:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ee532b22aba' User entered 'No (N)'	System	17 Sep 2020 03:49:28
	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:49:24', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ee532b22aba' User entered '16 Sep 2020 20:49'	System	17 Sep 2020 03:49:28
	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 7'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:53', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303' User entered 'None (0)'	System	18 Sep 2020 02:17:19
	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303' User entered 'None (0)'	System	18 Sep 2020 02:17:19
	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303' User entered 'None (0)'	System	18 Sep 2020 02:17:19
	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:02', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303' User entered 'None (0)'	System	18 Sep 2020 02:17:19
	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303' User entered 'None (0)'	System	18 Sep 2020 02:17:19
	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303' User entered 'None (0)'	System	18 Sep 2020 02:17:19
	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303' User entered 'No (N)'	System	18 Sep 2020 02:17:19
	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303' User entered '17 Sep 2020 19:17'	System	18 Sep 2020 02:17:19
	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:00:45
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	25 Sep 2020 23:31:30

US3562157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:00:45
User entered '18 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	25 Sep 2020 23:31:30

US3562157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:00:45
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	25 Sep 2020 23:31:30

US3562157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:00:45
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Sep 2020 23:31:30

US3562157

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:00:56
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	25 Sep 2020 23:31:36

US3562157

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'l'	System	25 Sep 2020 23:31:36

US3562157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:01:23
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	25 Sep 2020 23:31:50

US3562157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:01:23
User entered '25 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	25 Sep 2020 23:31:50

US3562157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:01:23
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	25 Sep 2020 23:31:50

US3562157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:01:23
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Sep 2020 23:31:50

US3562157

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:01:32
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	25 Sep 2020 23:31:56

US3562157

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'l'	System	25 Sep 2020 23:31:56

US3562157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:02:50
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 23:47:55

US3562157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:02:50
User entered '2 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 23:47:55

US3562157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:02:50
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 23:47:55

US3562157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:02:50
User entered empty.	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 23:47:55

US3562157

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:02:59
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	02 Oct 2020 23:48:03

US3562157

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	02 Oct 2020 23:48:03

US3562157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:06
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:31:28

US3562157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:06
User entered '14 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:31:28

US3562157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:06
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:31:28

US3562157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'VISIT2'	System	15 Oct 2020 17:31:28

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '14 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '16:02'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '14 Oct 2020 16:02'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '98.3' F	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '69'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'bpm'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '16'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'breaths/min'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '106'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '68'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '14 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '17:18'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '14 Oct 2020 17:18'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '98.3' F	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '66'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'bpm'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '16'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'breaths/min'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '122'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '74'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:26

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:06:28
User closed query 'Please confirm response. Per source, symptom driven PE was not performed as it was not clinically indicated. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 22:06:25
Query 'Please confirm response. Per source, symptom driven PE was not performed as it was not clinically indicated. Please update as applicable. ' answered with 'please see progress note ! physical exam was completed for lymph node and did not complete for other as it was not clinically indicated ' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 16:09:30
User opened query 'Please confirm response. Per source, symptom driven PE was not performed as it was not clinically indicated. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 15:42:40
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:27:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:27:43
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:06:33
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:36

US3562157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:06:30
DataPoint Un-verified.	Dhwani Shah (b) (4)	18 Nov 2020 22:27:43
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	18 Nov 2020 22:27:43
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:06:33
User entered empty.	Dhwani Shah (b) (4)	15 Oct 2020 17:36:36

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

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)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered '16:45'	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '14 Oct 2020 16:45'	System	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered 'ONCE'	System	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:55

US3562157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under Visit 2 Day 29 Visit with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 12:54:12
	(b) (4), (b) (6)	18 Nov 2020 17:08:08
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under Visit 2 Day 29 Visit with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'per protocol immunogenicity sample must be collected at each visit. all samples send to PPD central lab as well ! Submitted DCF 2 weeks before and PPD need to update from their side ! Site has confirmation that PPD central lab received all samples for visit 1 and visit 2 ' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under Visit 2 Day 29 Visit with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM). User entered '14 Oct 2020'	Dhwani Shah (b) (4)	26 Oct 2020 20:25:29
	(b) (4), (b) (6)	23 Oct 2020 14:40:31
	Dhwani Shah (b) (4)	15 Oct 2020 17:36:55

US3562157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:08
User entered '16:10'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:55

US3562157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '14 Oct 2020 16:10'	System	15 Oct 2020 17:36:55

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:20:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:56
User entered '14 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:56
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:56
User entered '16:27'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '14 Oct 2020 16:27'	System	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:56
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:56
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:09:09
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:37:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	15 Oct 2020 17:37:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:19:45', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8ae2e186-4bce-4597-b3cc-206c9c72bbbf' User entered 'Yes (Y)'	System	15 Oct 2020 00:20:10
	System	15 Oct 2020 00:20:10

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:19:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8ae2e186-4bce-4597-b3cc-206c9c72bbbf' User entered '98.3'	System	15 Oct 2020 00:20:10
	System	15 Oct 2020 00:20:10

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8ae2e186-4bce-4597-b3cc-206c9c72bbbf' User entered 'No (N)'	System	15 Oct 2020 00:20:10
	System	15 Oct 2020 00:20:10

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:08', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8ae2e186-4bce-4597-b3cc-206c9c72bbbf' User entered '14 Oct 2020 17:20'	System	15 Oct 2020 00:20:10
	System	15 Oct 2020 00:20:10

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Oct 2020 17:05'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Oct 2020 19:35'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:10', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'feb8ce87-4a05-4842-af38-e76c84b852a2'	System	15 Oct 2020 04:30:32
User entered 'Yes (Y)'	System	15 Oct 2020 04:30:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:16', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'feb8ce87-4a05-4842-af38-e76c84b852a2'	System	15 Oct 2020 04:30:32
User entered '98.6'	System	15 Oct 2020 04:30:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'feb8ce87-4a05-4842-af38-e76c84b852a2'	System	15 Oct 2020 04:30:32
User entered 'No (N)'	System	15 Oct 2020 04:30:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:29', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'feb8ce87-4a05-4842-af38-e76c84b852a2'	System	15 Oct 2020 04:30:32
User entered '14 Oct 2020 21:30'	System	15 Oct 2020 04:30:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Oct 2020 20:30'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 2'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:16:38', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4' User entered 'Yes (Y)'	System	16 Oct 2020 04:17:15
	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:16:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4' User entered '98.8'	System	16 Oct 2020 04:17:15
	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:16:51', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4' User entered 'Yes (Y)'	System	16 Oct 2020 04:17:15
	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated con med 12' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 07:09:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:16:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4'	(b) (4)	
User entered '1'	System	16 Oct 2020 04:17:15
	System	16 Oct 2020 04:17:15
	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:16:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4' User entered '0'	System	16 Oct 2020 04:17:15
	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:17:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4' User entered '15 Oct 2020 21:17'	System	16 Oct 2020 04:17:15
	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 3'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:43:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e2daabe2-b07a-4196-b351-e3928618fd37' User entered 'Yes (Y)'	System	17 Oct 2020 04:43:47
	System	17 Oct 2020 04:43:47

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:43:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e2daabe2-b07a-4196-b351-e3928618fd37' User entered '97.7'	System	17 Oct 2020 04:43:47
	System	17 Oct 2020 04:43:47

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:43:36', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e2daabe2-b07a-4196-b351-e3928618fd37'	System	17 Oct 2020 04:43:47
User entered 'No (N)'	System	17 Oct 2020 04:43:47

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:43:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e2daabe2-b07a-4196-b351-e3928618fd37' User entered '16 Oct 2020 21:43'	System	17 Oct 2020 04:43:47
	System	17 Oct 2020 04:43:47

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 4'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:08', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8897d32d-cbc3-4980-b618-ccf3ba8c544f' User entered 'Yes (Y)'	System	18 Oct 2020 04:51:32
	System	18 Oct 2020 04:51:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:19', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8897d32d-cbc3-4980-b618-ccf3ba8c544f' User entered '97.6'	System	18 Oct 2020 04:51:32
	System	18 Oct 2020 04:51:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:23', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8897d32d-cbc3-4980-b618-ccf3ba8c544f' User entered 'No (N)'	System	18 Oct 2020 04:51:32
	System	18 Oct 2020 04:51:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8897d32d-cbc3-4980-b618-ccf3ba8c544f' User entered '17 Oct 2020 21:51'	System	18 Oct 2020 04:51:32
	System	18 Oct 2020 04:51:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 5'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:01', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9f9bde2-e8ba-49f7-8f1e-10cfbdf9475c' User entered 'Yes (Y)'	System	19 Oct 2020 02:32:17
	System	19 Oct 2020 02:32:17

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9f9bde2-e8ba-49f7-8f1e-10cfbdf9475c' User entered '97.9'	System	19 Oct 2020 02:32:17
	System	19 Oct 2020 02:32:17

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9f9bde2-e8ba-49f7-8f1e-10cfbdf9475c'	System	19 Oct 2020 02:32:17
User entered 'No (N)'	System	19 Oct 2020 02:32:17

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:13', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9f9bde2-e8ba-49f7-8f1e-10cfbdf9475c' User entered '18 Oct 2020 19:32'	System	19 Oct 2020 02:32:17
	System	19 Oct 2020 02:32:17

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 6'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '21534e09-3e3d-4a72-b413-2f728305abfa' User entered 'Yes (Y)'	System	20 Oct 2020 05:00:27
	System	20 Oct 2020 05:00:27

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:15', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '21534e09-3e3d-4a72-b413-2f728305abfa' User entered '98.7'	System	20 Oct 2020 05:00:27
	System	20 Oct 2020 05:00:27

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '21534e09-3e3d-4a72-b413-2f728305abfa' User entered 'No (N)'	System	20 Oct 2020 05:00:27
	System	20 Oct 2020 05:00:27

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:23', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '21534e09-3e3d-4a72-b413-2f728305abfa' User entered '19 Oct 2020 22:00'	System	20 Oct 2020 05:00:27
	System	20 Oct 2020 05:00:27

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 7'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:29', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9ba9f35-821b-4fec-930d-158340e2f4d7'	System	21 Oct 2020 04:47:46
User entered 'Yes (Y)'	System	21 Oct 2020 04:47:46

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:34', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9ba9f35-821b-4fec-930d-158340e2f4d7' User entered '97.7'	System	21 Oct 2020 04:47:46
	System	21 Oct 2020 04:47:46

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:39', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9ba9f35-821b-4fec-930d-158340e2f4d7'	System	21 Oct 2020 04:47:46
User entered 'No (N)'	System	21 Oct 2020 04:47:46

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9ba9f35-821b-4fec-930d-158340e2f4d7'	System	21 Oct 2020 04:47:46
User entered '20 Oct 2020 21:47'	System	21 Oct 2020 04:47:46

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4b41b15e-c307-48a5-a68c-b48ea8527b06'	System	15 Oct 2020 00:20:46
User entered 'None (1)'	System	15 Oct 2020 00:20:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4b41b15e-c307-48a5-a68c-b48ea8527b06' User entered 'No (N)'	System	15 Oct 2020 00:20:46
	System	15 Oct 2020 00:20:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:30', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4b41b15e-c307-48a5-a68c-b48ea8527b06' User entered 'No (N)'	System	15 Oct 2020 00:20:46
	System	15 Oct 2020 00:20:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:37', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4b41b15e-c307-48a5-a68c-b48ea8527b06'	System	15 Oct 2020 00:20:46
User entered 'None (1)'	System	15 Oct 2020 00:20:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4b41b15e-c307-48a5-a68c-b48ea8527b06' User entered '14 Oct 2020 17:20'	System	15 Oct 2020 00:20:46
	System	15 Oct 2020 00:20:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Oct 2020 17:05'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Oct 2020 19:35'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f09712c4-bc77-4690-b5c4-159434694e72'	System	15 Oct 2020 04:31:45
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 04:31:45

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:47', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f09712c4-bc77-4690-b5c4-159434694e72'	System	15 Oct 2020 04:31:45
User entered 'No (N)'	System	15 Oct 2020 04:31:45

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f09712c4-bc77-4690-b5c4-159434694e72' User entered 'No (N)'	System	15 Oct 2020 04:31:45
	System	15 Oct 2020 04:31:45

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f09712c4-bc77-4690-b5c4-159434694e72'	System	15 Oct 2020 04:31:45
User entered 'None (1)'	System	15 Oct 2020 04:31:45

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f09712c4-bc77-4690-b5c4-159434694e72' User entered '14 Oct 2020 21:31'	System	15 Oct 2020 04:31:45
	System	15 Oct 2020 04:31:45

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Oct 2020 20:30'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 2'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:17:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e'	System	16 Oct 2020 04:21:37
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:17:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e' User entered 'Yes (Y)'	System	16 Oct 2020 04:21:37
	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

Please record - REDNESS AT INJECTION SITE (in mm)

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:20:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e' User entered '125'	System	16 Oct 2020 04:21:37
	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:20:56', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e' User entered 'Yes (Y)'	System	16 Oct 2020 04:21:37
	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:21:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e' User entered '25'	System	16 Oct 2020 04:21:37
	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:21:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e' User entered 'None (1)'	System	16 Oct 2020 04:21:37
	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:21:35', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e' User entered '15 Oct 2020 21:21'	System	16 Oct 2020 04:21:37
	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 3'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:43:51', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c'	System	17 Oct 2020 04:44:46
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c' User entered 'No (N)'	System	17 Oct 2020 04:44:46
	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c' User entered 'Yes (Y)'	System	17 Oct 2020 04:44:46
	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c' User entered '2'	System	17 Oct 2020 04:44:46
	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:30', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c' User entered 'None (1)'	System	17 Oct 2020 04:44:46
	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c' User entered '16 Oct 2020 21:44'	System	17 Oct 2020 04:44:46
	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 4'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:41', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867'	System	18 Oct 2020 04:52:08
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:45', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867' User entered 'No (N)'	System	18 Oct 2020 04:52:08
	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:48', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867' User entered 'Yes (Y)'	System	18 Oct 2020 04:52:08
	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:54', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867' User entered '2'	System	18 Oct 2020 04:52:08
	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867' User entered 'None (1)'	System	18 Oct 2020 04:52:08
	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867' User entered '17 Oct 2020 21:52'	System	18 Oct 2020 04:52:08
	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 5'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:24', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacce'	System	19 Oct 2020 02:33:00
User entered 'None (1)'	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacce'	System	19 Oct 2020 02:33:00
User entered 'No (N)'	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:33', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacce'	System	19 Oct 2020 02:33:00
User entered 'Yes (Y)'	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:39', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacce'	System	19 Oct 2020 02:33:00
User entered '2'	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:45', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacce'	System	19 Oct 2020 02:33:00
User entered 'None (1)'	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:56', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacce'	System	19 Oct 2020 02:33:00
User entered '18 Oct 2020 19:32'	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 6'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:29', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb'	System	20 Oct 2020 05:01:00
User entered 'None (1)'	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb' User entered 'No (N)'	System	20 Oct 2020 05:01:00
	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:35', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb' User entered 'Yes (Y)'	System	20 Oct 2020 05:01:00
	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb' User entered '1'	System	20 Oct 2020 05:01:00
	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:47', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb' User entered 'None (1)'	System	20 Oct 2020 05:01:00
	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:55', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb' User entered '19 Oct 2020 22:00'	System	20 Oct 2020 05:01:00
	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 7'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '45d1d8a8-b965-4249-82d9-65be3f52690a' User entered 'None (1)'	System	21 Oct 2020 04:48:15
	System	21 Oct 2020 04:48:15

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:53', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '45d1d8a8-b965-4249-82d9-65be3f52690a' User entered 'No (N)'	System	21 Oct 2020 04:48:15
	System	21 Oct 2020 04:48:15

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '45d1d8a8-b965-4249-82d9-65be3f52690a' User entered 'No (N)'	System	21 Oct 2020 04:48:15
	System	21 Oct 2020 04:48:15

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '45d1d8a8-b965-4249-82d9-65be3f52690a' User entered 'None (1)'	System	21 Oct 2020 04:48:15
	System	21 Oct 2020 04:48:15

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '45d1d8a8-b965-4249-82d9-65be3f52690a' User entered '20 Oct 2020 21:48'	System	21 Oct 2020 04:48:15
	System	21 Oct 2020 04:48:15

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:08', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458' User entered 'None (0)'	System	15 Oct 2020 00:21:41
	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:13', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458' User entered 'None (0)'	System	15 Oct 2020 00:21:41
	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:15', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458' User entered 'None (0)'	System	15 Oct 2020 00:21:41
	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:18', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458' User entered 'None (0)'	System	15 Oct 2020 00:21:41
	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:21', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458' User entered 'None (0)'	System	15 Oct 2020 00:21:41
	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:24', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458' User entered 'None (0)'	System	15 Oct 2020 00:21:41
	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458'	System	15 Oct 2020 00:21:41
User entered 'No (N)'	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:37', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458' User entered '14 Oct 2020 17:21'	System	15 Oct 2020 00:21:41
	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Oct 2020 17:05'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Oct 2020 19:35'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:48', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330' User entered 'None (0)'	System	15 Oct 2020 04:32:29
	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330' User entered 'None (0)'	System	15 Oct 2020 04:32:29
	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330' User entered 'None (0)'	System	15 Oct 2020 04:32:29
	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:32:02', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330' User entered 'None (0)'	System	15 Oct 2020 04:32:29
	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:32:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330' User entered 'None (0)'	System	15 Oct 2020 04:32:29
	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:32:07', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330' User entered 'None (0)'	System	15 Oct 2020 04:32:29
	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:32:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330' User entered 'No (N)'	System	15 Oct 2020 04:32:29
	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:32:26', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330' User entered '14 Oct 2020 21:32'	System	15 Oct 2020 04:32:29
	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '14 Oct 2020 20:30'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 2'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015'	System	16 Oct 2020 04:22:44
User entered 'No interference with activity (1)'	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015'	System	16 Oct 2020 04:22:44
User entered 'Some interference with activity (2)'	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015' User entered 'None (0)'	System	16 Oct 2020 04:22:44
	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015' User entered 'None (0)'	System	16 Oct 2020 04:22:44
	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:19', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015' User entered 'None (0)'	System	16 Oct 2020 04:22:44
	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:22', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015' User entered 'None (0)'	System	16 Oct 2020 04:22:44
	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:26', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015' User entered 'No (N)'	System	16 Oct 2020 04:22:44
	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:41', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015' User entered '15 Oct 2020 21:22'	System	16 Oct 2020 04:22:44
	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 3'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79' User entered 'None (0)'	System	17 Oct 2020 04:45:19
	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:53', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79' User entered 'None (0)'	System	17 Oct 2020 04:45:19
	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79' User entered 'None (0)'	System	17 Oct 2020 04:45:19
	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:45:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79' User entered 'None (0)'	System	17 Oct 2020 04:45:19
	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:45:02', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79' User entered 'None (0)'	System	17 Oct 2020 04:45:19
	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:45:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79' User entered 'None (0)'	System	17 Oct 2020 04:45:19
	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:45:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79'	System	17 Oct 2020 04:45:19
User entered 'No (N)'	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:45:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79' User entered '16 Oct 2020 21:45'	System	17 Oct 2020 04:45:19
	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 4'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73' User entered 'None (0)'	System	18 Oct 2020 04:52:37
	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73' User entered 'None (0)'	System	18 Oct 2020 04:52:37
	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:18', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73' User entered 'None (0)'	System	18 Oct 2020 04:52:37
	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73' User entered 'None (0)'	System	18 Oct 2020 04:52:37
	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73' User entered 'None (0)'	System	18 Oct 2020 04:52:37
	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73' User entered 'None (0)'	System	18 Oct 2020 04:52:37
	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73' User entered 'No (N)'	System	18 Oct 2020 04:52:37
	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:34', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73' User entered '17 Oct 2020 21:52'	System	18 Oct 2020 04:52:37
	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 5'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167' User entered 'None (0)'	System	19 Oct 2020 02:33:26
	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:02', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167' User entered 'None (0)'	System	19 Oct 2020 02:33:26
	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167' User entered 'None (0)'	System	19 Oct 2020 02:33:26
	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:07', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167' User entered 'None (0)'	System	19 Oct 2020 02:33:26
	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167' User entered 'None (0)'	System	19 Oct 2020 02:33:26
	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167' User entered 'None (0)'	System	19 Oct 2020 02:33:26
	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:15', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167' User entered 'No (N)'	System	19 Oct 2020 02:33:26
	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:23', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167' User entered '18 Oct 2020 19:33'	System	19 Oct 2020 02:33:26
	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 6'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348' User entered 'None (0)'	System	20 Oct 2020 05:01:32
	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348' User entered 'None (0)'	System	20 Oct 2020 05:01:32
	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348' User entered 'None (0)'	System	20 Oct 2020 05:01:32
	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348' User entered 'None (0)'	System	20 Oct 2020 05:01:32
	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348' User entered 'None (0)'	System	20 Oct 2020 05:01:32
	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:13', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348' User entered 'None (0)'	System	20 Oct 2020 05:01:32
	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348' User entered 'No (N)'	System	20 Oct 2020 05:01:32
	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348' User entered '19 Oct 2020 22:01'	System	20 Oct 2020 05:01:32
	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 7'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25' User entered 'None (0)'	System	21 Oct 2020 04:48:48
	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:21', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25' User entered 'None (0)'	System	21 Oct 2020 04:48:48
	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25' User entered 'None (0)'	System	21 Oct 2020 04:48:48
	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25' User entered 'None (0)'	System	21 Oct 2020 04:48:48
	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:30', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25' User entered 'None (0)'	System	21 Oct 2020 04:48:48
	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25' User entered 'None (0)'	System	21 Oct 2020 04:48:48
	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:36', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25'	System	21 Oct 2020 04:48:48
User entered 'No (N)'	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:45', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25'	System	21 Oct 2020 04:48:48
User entered '20 Oct 2020 21:48'	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:13:29
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 16:31:36

US3562157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:13:29
User entered '22 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 16:31:36

US3562157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:13:29
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 16:31:36

US3562157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:13:29
User entered empty.	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 16:31:36

US3562157

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:13:38
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 16:31:40

US3562157

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'l'	System	22 Oct 2020 16:31:40

US3562157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:14:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	28 Oct 2020 22:40:33

US3562157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:14:08
User entered '28 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	28 Oct 2020 22:40:33

US3562157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:14:08
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	28 Oct 2020 22:40:33

US3562157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:14:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	28 Oct 2020 22:40:33

US3562157

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:14:17
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	28 Oct 2020 22:40:36

US3562157

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'l'	System	28 Oct 2020 22:40:36

US3562157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:17:18
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 20:16:57

US3562157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:17:18
User entered '05 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 20:16:57

US3562157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:17:18
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 20:16:57

US3562157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:17:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 20:16:57

US3562157

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:17:27
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 20:17:00

US3562157

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	11 Nov 2020 20:17:00

US3562157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:19:21
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:24

US3562157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:19:21
User entered '11 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:24

US3562157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:19:21
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:24

US3562157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'VISIT3'	System	11 Nov 2020 23:06:24

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:41:44
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:41:44
User entered '11 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:41:44
User entered '13:03'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '11 Nov 2020 13:03'	System	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:41:44
User entered '98.9' F	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:41:44
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:41:44
User entered empty.	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:41:44
User entered '72'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'bpm'	System	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:41:44
User entered '14'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'breaths/min'	System	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:41:44
User entered '105'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:41:44
User entered '71'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'mmHg'	System	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:26

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 22:48:11
User closed query 'Please confirm response. Per source, symptom directed PE was not done. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:48:04
Query 'Please confirm response. Per source, symptom directed PE was not done. Please update as applicable. ' answered with 'physical was done please see progress note Thank you' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:23:15
User opened query 'Please confirm response. Per source, symptom directed PE was not done. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:20:54
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:52

US3562157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 22:48:11
User entered '11 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:06:52

US3562157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:21:19
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:07:04

US3562157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:21:19
User entered '11 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:07:04

US3562157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:21:19
User entered '13:10'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:07:04

US3562157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '11 Nov 2020 13:10'	System	11 Nov 2020 23:07:04

US3562157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:21:28
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	11 Nov 2020 23:07:07

US3562157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	11 Nov 2020 23:07:07

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 64'	System	12 Sep 2020 00:19:07

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:11:26', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36'	System	11 Nov 2020 20:12:27
User entered 'Yes (Y)'	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:11:33', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36'	System	11 Nov 2020 20:12:27
User entered 'No (N)'	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

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)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:11:37', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36'	System	11 Nov 2020 20:12:27
User entered 'No (N)'	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

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)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:11:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36'	System	11 Nov 2020 20:12:27
User entered 'Yes (Y)'	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:11:56', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36'	System	11 Nov 2020 20:12:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:12:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36' User entered '11 Nov 2020 13:12:17'	System	11 Nov 2020 20:12:27
	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered '11 Nov 2020 00:01'	System	12 Sep 2020 00:19:07

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:24:27
Data entry locked.	System	12 Sep 2020 00:19:07
User entered '15 Nov 2020 23:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 71'	System	12 Sep 2020 00:19:07

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

Have you been exposed to someone with 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 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Please 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 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Please 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 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Please 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 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03
Data entry locked.	System	12 Sep 2020 00:19:07
User entered '18 Nov 2020 00:01'	System	12 Sep 2020 00:19:07

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:58:03
Data entry locked.	System	12 Sep 2020 00:19:07
User entered '22 Nov 2020 23:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-22T09:13:50', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd566062e-b03a-4914-ab1c-0ace301e1e54'	System	22 Nov 2020 16:14:08
User entered 'No (N)'	System	22 Nov 2020 16:14:08

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

Have you been exposed to someone with 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 19:25:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-22T09:13:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd566062e-b03a-4914-ab1c-0ace301e1e54'	System	22 Nov 2020 16:14:08
User entered 'No (N)'	System	22 Nov 2020 16:14:08

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-22T09:14:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd566062e-b03a-4914-ab1c-0ace301e1e54' User entered '22 Nov 2020 09:14:05'	System	22 Nov 2020 16:14:08
	System	22 Nov 2020 16:14:08

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-12-02T18:06:26', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '76200412-f39b-4aab-9a8d-f8f23a5ab90a'	System	03 Dec 2020 01:07:22
User entered 'Yes (Y)'	System	03 Dec 2020 01:07:22

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

Have you been exposed to someone with 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 19:25:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-12-02T18:06:33', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '76200412-f39b-4aab-9a8d-f8f23a5ab90a'	System	03 Dec 2020 01:07:22
User entered 'No (N)'	System	03 Dec 2020 01:07:22

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[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 19:25:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-12-02T18:06:37', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '76200412-f39b-4aab-9a8d-f8f23a5ab90a'	System	03 Dec 2020 01:07:22
User entered 'No (N)'	System	03 Dec 2020 01:07:22

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-12-02T18:06:45', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '76200412-f39b-4aab-9a8d-f8f23a5ab90a'	System	03 Dec 2020 01:07:22
User entered 'Yes (Y)'	System	03 Dec 2020 01:07:22

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Please 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 19:25:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-12-02T18:06:56', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '76200412-f39b-4aab-9a8d-f8f23a5ab90a'	System	03 Dec 2020 01:07:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Dec 2020 01:07:22

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-12-02T18:07:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '76200412-f39b-4aab-9a8d-f8f23a5ab90a' User entered '02 Dec 2020 18:07:12'	System	03 Dec 2020 01:07:22
	System	03 Dec 2020 01:07:22

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:00:40
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	15 Apr 2021 20:30:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	15 Apr 2021 20:30:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	15 Apr 2021 20:30:02
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:30:02
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:33:45

US3562157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:00:40
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	15 Apr 2021 20:30:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	15 Apr 2021 20:30:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	15 Apr 2021 20:30:02
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:30:02
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User entered empty.	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:33:45

US3562157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:00:40
DataPoint Verified.	(b) (4)	
	(u) (4), (u) (6)	15 Apr 2021 20:30:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	15 Apr 2021 20:30:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	15 Apr 2021 20:30:02
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:30:02
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
	(b) (4)	
User entered empty.	Dhwani Shah (b) (4)	17 Mar 2021 22:33:45
	(b) (4)	

US3562157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:00:40
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	15 Apr 2021 20:30:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	15 Apr 2021 20:30:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	15 Apr 2021 20:30:02
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:30:02
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User entered empty.	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:33:45

US3562157

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:00:40
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	15 Apr 2021 20:30:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	15 Apr 2021 20:30:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	15 Apr 2021 20:30:12
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:30:12
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4)	17 Mar 2021 22:33:52

US3562157

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	15 Apr 2021 20:30:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	15 Apr 2021 20:30:12
User entered empty.	System	17 Mar 2021 22:33:52

US3562157

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:20:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	06 Nov 2020 00:48:06
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:57

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:04
User entered 'USA-US071-2020-mRNA-1273-P301000002'	System	06 Nov 2020 22:57:56
User entered 'New'	(b) (4), (b) (6)	06 Nov 2020 22:57:56

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms unspecified malignancy and site unspecified NEC, PT: Pelvic neoplasm, LLT: Pelvic neoplasm - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 05:52:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 05:52:51
Data point term sent to Coder	System	06 Nov 2020 00:50:04
User entered 'PELVIC CANCER'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '04 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	10 Nov 2020 21:04:05
User entered '04 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User entered empty.	System	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 23:11:32
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' answered with 'Please note pt is already out of study since last year and can not get end date ' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	22 Apr 2021 15:09:55
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 14:43:15
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:58:58
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 17:00:27
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.' canceled (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 17:00:15
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)	13 Nov 2020 15:31:55
User entered empty.	System	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Grade 4 (Grade 4)'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 00:50:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 00:50:24
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:24
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 00:50:03
User entered empty.	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
DataPoint Un-verified.	Dhwani Shah (b) (4)	09 Feb 2021 19:30:51
User entered '0' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	09 Feb 2021 19:30:51
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	26 Jan 2021 06:35:14
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'site was unable to received medical records and pt does not have any information and as per site knowladge its none. will update data incase site received medical records' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 00:38:36
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 22:20:15
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[None](#)

Audit	User	Time (GMT)
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'medical treatment procedure is unknown ' (Site from DM).	(u) (4), (b) (6)	15 Mar 2021 12:06:54
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	Dhwani Shah (b) (4)	09 Mar 2021 21:28:22
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:38:38
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:30:13
DataPoint Un-verified.	Dhwani Shah (b) (4)	09 Feb 2021 19:30:51
User entered '1' reason for change: Data Entry Error	Dhwani Shah (b) (4)	09 Feb 2021 19:30:51
DataPoint Verified.	(u) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User closed query 'PV Query: Please provide the final events outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 20:03:25
Query 'PV Query: Please provide the final events outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'no further information available ! patient is out from study and site is unable to receive data ! confirmed as it is ' (Site from Safety).	Dhwani Shah (b) (4)	05 Feb 2021 23:48:47
User opened query 'PV Query: Please provide the final events outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:59:45
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:40:23
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'OUTCOME IS UNKNOWN SITE IS NOT ABLE TO RECEIVE MEDICAL RECORDS AND PT IS OUT FROM STUDY ' (Site from Safety).	Dhwani Shah (b) (4)	29 Jan 2021 23:12:52

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:36:04
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:59:46
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'site was unable to received medical records and pt does not have any information and as per site knowladge its none. will update data incase site received medical records' (Site from Safety). DataPoint Verified.	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 00:38:44
	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:31:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User closed query 'Per DM CLR: Narrative indicates that CT and IMMUNOCHEMISTRY was done. However, there is no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (u) (4), (u) (6)	01 Mar 2021 06:50:28
User closed query 'Per DM CLR: Narrative indicates Bibasilar Atelectasis. However, there is no corresponding AE record that match this information. Please review and update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:50:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:23:32
Query 'Per DM CLR: Narrative indicates Bibasilar Atelectasis. However, there is no corresponding AE record that match this information. Please review and update to record the corresponding AE as appropriate. Otherwise, clarify.' answered with 'UPDATED AE' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:51:45
Query 'Per DM CLR: Narrative indicates that CT and IMMUNOCHEMISTRY was done. However, there is no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' answered with 'immonochemistry is lab test not a procedure , added CT scan ' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:41:40
User opened query 'Per DM CLR: Narrative indicates that CT and IMMUNOCHEMISTRY was done. However, there is no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 19:32:45

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates Bibasilar Atelectasis. However, there is no corresponding AE record that match this information. Please review and update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 19:32:26
User closed query 'Please add results of CT performed on 05Nov2020. Please add results of the Cytology Report from 06Nov2020. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:45:52
User closed query 'PV Query: Please confirm no additional information is available after all measures have been exhausted to obtain information regarding the events until resolution. ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 20:03:28
Query 'PV Query: Please confirm no additional information is available after all measures have been exhausted to obtain information regarding the events until resolution. ' answered with 'no further information available ! ' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	05 Feb 2021 23:48:26
User opened query 'PV Query: Please confirm no additional information is available after all measures have been exhausted to obtain information regarding the events until resolution. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:59:33
User entered 'CT PERFORMED ON 05NOV2020 - imaged portions of the lowest thorax demonstrate inner bibasiller atelectasis, CYTOLOGY REPORT- 3 DIMENSIONAL CLUSTER OF PLEOMORPHIC CELLS. THE FOLLOWING TEST ARE PERFORMED AND SUPPORT THE DIAGNOSIS IMMUNOHISTOCHEMISTRY SHOWS THE CELLS OF INTEREST TO BE POSITIVE FOR MOC31, CK20;CDX2,SATB2 AND CK7. NEGATIVE FOR WT1, ER,P53, VIMENTIN' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:18:57
Query 'Please add results of CT performed on 05Nov2020. Please add results of the Cytology Report from 06Nov2020. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:17:34

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'CT performed on 05Nov2020 , cytology report- 3 dimensional cluster of pleomorphic cells. the following test are performed and support the diagnosis immunohistochemistry shows the cells of interest to be positive for moc31, ck20;cdx2,satb2 and ck7. negative for wt1, er,p53, vimentin' reason for change: Data Entry Error	Dhwani Shah (b) (4)	03 Feb 2021 20:17:22
User opened query 'Please add results of CT performed on 05Nov2020. Please add results of the Cytology Report from 06Nov2020. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:26:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:23:46
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.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:36:37
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 Nov 2020 22:35:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:36:42

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:36:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'still waiting for medical records, will updated once receive more info ' (Site from Safety).	Dhwani Shah (b) (4)	13 Nov 2020 17:58:52
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 'still waiting for medical records, will updated once receive more info ' (Site from Safety).	Dhwani Shah (b) (4)	13 Nov 2020 17:58:47
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)	13 Nov 2020 15:31:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:31:20
User entered 'PATENT WAS REFERED TO ONCOLOGIST'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User entered '1'	System	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User entered '1'	System	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:23:35
User entered 'USA-US071-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	10 Nov 2020 14:16:07

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Colorectal neoplasms malignant, PT: Colorectal cancer, LLT: Colorectal cancer - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 21:48:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 21:48:40
Data point term sent to Coder	System	11 Nov 2020 21:47:30
User entered 'colorectal cancer' reason for change:	Dhwani Shah (b) (4)	11 Nov 2020 21:46:39
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	11 Nov 2020 21:46:29
User closed query 'CDM Coding, please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Benign colonic neoplasm, Malignant neoplasm of colon etc)' (Site from System).	System	11 Nov 2020 21:46:13
Query 'CDM Coding, please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Benign colonic neoplasm, Malignant neoplasm of colon etc)' answered with 'will provide more info once received medical records ' (Site from System).	Dhwani Shah (b) (4)	11 Nov 2020 21:46:13
User opened query 'CDM Coding, please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Benign colonic neoplasm, Malignant neoplasm of colon etc)' (Site from System).	Coder Import (b) (4)	11 Nov 2020 04:13:44
Data point term sent to Coder	System	09 Nov 2020 17:17:14
User entered 'colon nodules'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '04 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	10 Nov 2020 21:04:25
User entered '04 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User entered empty.	System	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
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 DM).	(b) (4), (b) (6)	29 Apr 2021 23:11:57
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 'Please note pt is already out of study since last year and can not get end date . I will appreciate if you can stop requery as my answer will not change ..site can not get end date or can not confirm as pt is not in study anymore !' (Site from DM).	Dhwani Shah (b) (4)	22 Apr 2021 15:12:48
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 DM).	(b) (4), (b) (6)	22 Apr 2021 14:43:38
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
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.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 22:25:24
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)	13 Nov 2020 15:32:12
User entered empty.	System	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Grade 4 (Grade 4)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:21
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User closed query 'Per CDM: As this SAE is the reason for Study Discontinuation, kindly consider to update Action taken with Investigational product as "Investigational product withdrawn". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 03:10:17
Query 'Per CDM: As this SAE is the reason for Study Discontinuation, kindly consider to update Action taken with Investigational product as "Investigational product withdrawn". Please review and reconcile. Thank you. ' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	17 Mar 2021 22:37:27
DataPoint Un-verified.	Dhwani Shah (b) (4)	17 Mar 2021 22:37:07
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	17 Mar 2021 22:37:07
User opened query 'Per CDM: As this SAE is the reason for Study Discontinuation, kindly consider to update Action taken with Investigational product as "Investigational product withdrawn". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Not Applicable (NOT APPLICABLE)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:27:52
DataPoint Un-verified.	Dhwani Shah (b) (4)	09 Feb 2021 19:31:31
User entered '0' reason for change: Data Entry Error	Dhwani Shah (b) (4)	09 Feb 2021 19:31:31
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	26 Jan 2021 06:35:27
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'site was unable to received medical records and pt does not have any information and as per site knowladge its none. will update data incase site received medical records' (Site from DM).	Dhwani Shah (b) (4)	20 Jan 2021 00:38:50
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 22:20:42
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[None](#)

Audit	User	Time (GMT)
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'medical treatment procedure is unknown ' (Site from DM).	(u) (4), (b) (6)	15 Mar 2021 12:07:11
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	Dhwani Shah (b) (4)	09 Mar 2021 21:28:31
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:39:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:27:55
DataPoint Un-verified.	Dhwani Shah (b) (4)	09 Feb 2021 19:31:31
User entered '1' reason for change: Data Entry Error	Dhwani Shah (b) (4)	09 Feb 2021 19:31:31
DataPoint Verified.	(u) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (u) (4), (b) (6)	01 Feb 2021 15:41:05
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'UNABLE TO RECEIVED MEDICAL RECORDS AND PT IS OUT OF STUDY ' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	29 Jan 2021 23:13:29
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:44:46
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:59:57
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'site was unable to received medical records and pt does not have any information and as per site knowladge its none. will update data incase site received medical records' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 00:38:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:32:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User closed query 'Per DM CLR: Narrative = CYTOLOGY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). Query 'Per DM CLR: Narrative = CYTOLOGY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 07:05:35
User opened query 'Per DM CLR: Narrative = CYTOLOGY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). User closed query 'Per DM CLR: Narrative indicates that Chemotherapy was started. However, there is no corresponding record on either ConMed or ConProc page that match the information. Please update to record the details of Chemotherapy as appropriate. Otherwise, clarify.' (Site from DM).	Dhwani Shah (b) (4)	10 Mar 2021 17:59:43
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 06:39:40
	(b) (4), (b) (6)	02 Mar 2021 12:23:15
Query 'Per DM CLR: Narrative indicates that Chemotherapy was started. However, there is no corresponding record on either ConMed or ConProc page that match the information. Please update to record the details of Chemotherapy as appropriate. Otherwise, clarify.' answered with 'as per previous response site was unable to receive medical records and pt is withdrew consent , those information is unknown' (Site from DM).	Dhwani Shah (b) (4)	25 Feb 2021 21:28:29
User opened query 'Per DM CLR: Narrative indicates that Chemotherapy was started. However, there is no corresponding record on either ConMed or ConProc page that match the information. Please update to record the details of Chemotherapy as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 18:43:45
	(b) (4), (b) (6)	22 Feb 2021 19:31:32

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Please provide results from CT scan on 04Nov2020 and Cytology Report from 06Nov2020. Also please add patient self reported that 8 Sessions of Chemotherapy were started on 23Nov2020 per progress note from 01Dec2020. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:46:12
Query 'Please provide results from CT scan on 04Nov2020 and Cytology Report from 06Nov2020. Also please add patient self reported that 8 Sessions of Chemotherapy were started on 23Nov2020 per progress note from 01Dec2020. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:19:47
User entered 'PATIENT SELF REPORTED THAT 8 SESSIONS OF CHEMOTHERAPY WERE STARTED ON 23NOV2020, CT and cytology report was added under AE # 1' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	03 Feb 2021 20:19:41
User entered 'patient self reported that 8 Sessions of Chemotherapy were started on 23Nov2020' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	02 Feb 2021 19:26:20
User opened query 'Please provide results from CT scan on 04Nov2020 and Cytology Report from 06Nov2020. Also please add patient self reported that 8 Sessions of Chemotherapy were started on 23Nov2020 per progress note from 01Dec2020. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:28:25
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:26:54
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:41:30
User closed query 'PV Query: Please provide signs and symptoms for the events. If none please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:41:24

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:41:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'UNABLE TO RECEIVED MEDICAL RECORDS AND PT IS OUT OF STUDY ' (Site from Safety).	Dhwani Shah (b) (4)	29 Jan 2021 23:13:40
Query 'PV Query: Please provide signs and symptoms for the events. If none please state so.' answered with 'UNABLE TO RECEIVED MEDICAL RECORDS AND PT IS OUT OF STUDY ' (Site from Safety).	Dhwani Shah (b) (4)	29 Jan 2021 23:13:37
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 'UNABLE TO RECEIVED MEDICAL RECORDS AND PT IS OUT OF STUDY ' (Site from Safety).	Dhwani Shah (b) (4)	29 Jan 2021 23:13:33
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:45:11
User opened query 'PV Query: Please provide signs and symptoms for the events. If none please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:45:02

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:44:34
User closed query 'PV Query: Please provide signs and symptoms for the events. If none please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:00:06
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:00:03
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:59:59
Query 'PV Query: Please provide signs and symptoms for the events. If none please state so.' answered with 'site was unable to received medical records and pt does not have any information and as per site knowledge its none. will update data incase site received medical records' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 00:39:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'site was unable to received medical records and pt does not have any information and as per site knowledge its none. will update data incase site received medical records' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 00:39:04

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
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 'site was unable to received medical records and pt does not have any information and as per site knowledge its none. will update data incase site received medical records' (Site from Safety).	Dhwani Shah (b) (4)	20 Jan 2021 00:39:00
User opened query 'PV Query: Please provide signs and symptoms for the events. If none please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:36:15
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:32:44
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)	13 Nov 2020 15:32:23
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 17:17:27
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	09 Nov 2020 17:17:27
User entered 'Patient was referred to oncologist' reason for change: Data Entry Error	Dhwani Shah (b) (4)	09 Nov 2020 17:17:27
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 17:16:57
User entered empty.	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57

PRODUCTION RELEASE (v12.003
EAB) (1725)

1172 of 1723

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User entered 'I'	System	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User entered 'I'	System	09 Nov 2020 17:16:57

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
Reviewed for Safety.	(b) (4) (u) (4), (u) (6)	18 Mar 2021 14:16:08
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:28:43
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 16:09:46

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 21:39:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 21:39:48
Data point term sent to Coder	System	16 Nov 2020 21:38:51
User entered 'shingles'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '17 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User entered empty.	System	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '07 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User entered empty.	System	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'None (NONE)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:29:20
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Jan 2021 00:41:54
User entered '0' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Jan 2021 00:41:54
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 17:27:14
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Nov 2020 21:38:46
User entered '1' reason for change: Data Entry Error	Dhwani Shah (b) (4)	16 Nov 2020 21:38:46
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	16 Nov 2020 21:38:41
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:29:21
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Jan 2021 00:41:54
User entered '1' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Jan 2021 00:41:54
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User entered '0'	System	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44
User entered 'I'	System	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:44

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:13
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 13:57:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 13:57:28
Data point term sent to Coder	System	01 Feb 2021 13:57:18
User entered 'injection site pain'	Dhwani Shah (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:16
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:21
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:24
User entered '23 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:28:59
User entered empty.	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User entered empty.	System	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:27
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:29
User entered '23 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:29:02
User entered empty.	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User entered empty.	System	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:33
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:36
User entered '0'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:38
User entered '0'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:40
User entered '0'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:42
User entered empty.	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:44
User entered empty.	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:48
User entered empty.	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:51
User entered empty.	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:54
User entered '0'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:56
User entered '0'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:31:58
User entered '0'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:32:00
User entered 'Related (RELATED)'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:32:03
User entered 'Related (RELATED)'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:32:05
User entered 'None (NONE)'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:32:10
User entered '0'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:32:11
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:32:17
User entered '0'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:32:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:32:22
User entered empty.	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User closed query 'Please add additional AEs noted in source: Ovarian Complex Cyst and Fibroid Uterus. ' (Site from CRA).	(b) (4)	
Query 'Please add additional AEs noted in source: Ovarian Complex Cyst and Fibroid Uterus. ' answered with 'updated' (Site from CRA).	(u) (4), (b) (6)	16 Feb 2021 18:46:59
User opened query 'Please add additional AEs noted in source: Ovarian Complex Cyst and Fibroid Uterus. ' (Site from CRA).	Dhwani Shah (b) (4)	03 Feb 2021 20:20:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:33:55
	(b) (4), (b) (6)	02 Feb 2021 18:32:24
User entered empty.	Dhwani Shah (b) (4)	01 Feb 2021 13:56:59
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User entered '0'	System	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47
User entered '0'	System	01 Feb 2021 13:56:59

US3562157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:44:47

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Atelectasis, LLT: Basilar atelectasis - version MedDRA\23.0.	Coder Import (b) (4)	28 Feb 2021 13:06:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Feb 2021 13:06:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:30:13
Data point term sent to Coder	System	25 Feb 2021 18:51:20
User entered 'Bibasilar Atelectasis.'	Dhwani Shah (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered '05 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User entered empty.	System	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (u) (4), (u) (6)	22 Mar 2021 14:23:33
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'end date is not availabl , pt is already withdrew consent and can not get update for AE ' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	17 Mar 2021 22:36:20
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:03:49
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:30:13
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 18:50:57
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 18:50:39
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 18:50:57
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	25 Feb 2021 18:50:57
User entered empty; reason for change Data Entry Error	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:57
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 18:50:39
User entered '05 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User entered empty.	System	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered 'None (NONE)'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered '0'	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	25 Feb 2021 18:50:57
User entered 'Unknown (UNKNOWN)'	Dhwani Shah (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	25 Feb 2021 21:30:13
User entered empty.	Dhwani Shah (b) (4) (b) (4)	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User entered '0'	System	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41
User entered 'I'	System	25 Feb 2021 18:50:39

US3562157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:20:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:41

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (+), (u) (6)	18 Nov 2020 17:28:06
User closed query 'Per CDM: Diary Dose 2 (1), Temperature day Log Line 3, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	(b) (4), (b) (6)	06 Nov 2020 04:19:39
' (Site from DM). Query 'Per CDM: Diary Dose 2 (1), Temperature day Log Line 3, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	Dhwani Shah (b) (4) (b) (4)	04 Nov 2020 23:49:59
' answered with 'con med line 8 and 9 ' (Site from DM). User opened query 'Per CDM: Diary Dose 2 (1), Temperature day Log Line 3, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	(b) (4), (b) (6)	03 Nov 2020 07:12:22
' (Site from DM).		

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:20:26

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

Audit	User	Time (GMT)
Query 'Per CDM: Diary Dose 1 (1), Temperature day Log Lines 2,6,7,8 and 9, ediary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' canceled (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:11:46
User opened query 'Per CDM: Diary Dose 1 (1), Temperature day Log Lines 2,6,7,8 and 9, ediary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	(b) (4), (b) (6)	03 Nov 2020 07:11:39
' (Site from DM). Query 'er CDM: Diary Dose 2 (1), Temperature day Log Line 3, ediary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	(b) (4), (b) (6)	03 Nov 2020 07:11:08
' canceled (Site from DM). User opened query 'er CDM: Diary Dose 2 (1), Temperature day Log Line 3, ediary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	(b) (4), (b) (6)	03 Nov 2020 07:10:54
' (Site from DM). User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:53:31

PRODUCTION RELEASE (v12.003
EAB) (1725)

1285 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: FOSAMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 21:56:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 21:56:32
Data point term sent to Coder	System	13 Sep 2020 21:55:12
User entered 'fosamax'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'osteoporosis'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '70'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'every week (QS)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2019'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '803 (803)'	System	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 21:56:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 21:56:32
Data point term sent to Coder	System	13 Sep 2020 21:55:12
User entered 'vitamin D3'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'osteoporosis'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '4000'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'IU (IU)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'once daily (QD)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2019'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '804 (804)'	System	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 17:44:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 17:44:30
Data point term sent to Coder	System	15 Oct 2020 17:44:01
Coding entries removed.	Dhwani Shah (b) (4)	15 Oct 2020 17:43:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 05:06:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 05:06:44
Data point term sent to Coder	System	13 Sep 2020 21:56:12
User entered 'folic acid'	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:32:30
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:43:47
User entered 'FOLIC ACID deficiency' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:43:40
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 03:02:39
User entered 'folic acid'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '400'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'once daily (QD)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2019'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '804 (804)'	System	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 04:55:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 04:55:44
Data point term sent to Coder	System	13 Sep 2020 21:57:13
User entered 'meltonin'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'insomnia'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '5'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'once daily (QD)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2008'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '804 (804)'	System	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 21:58:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 21:58:32
Data point term sent to Coder	System	13 Sep 2020 21:57:13
User entered 'lexapro'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'insomnia'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '20'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'once daily (QD)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2008'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '804 (804)'	System	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 06:16:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 06:16:41
Data point term sent to Coder	System	26 Sep 2020 17:45:49
Coding entries removed.	Dhwani Shah (b) (4)	26 Sep 2020 17:44:57
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 11:25:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 11:25:41
Data point term sent to Coder	System	13 Sep 2020 21:58:13
User entered 'estradiol cream'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 17:44:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Sep 2020 17:44:57
User entered 'post menopause syndrome' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:57
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Sep 2020 21:57:58
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '10'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'ug (ug)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '2 times a week'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Topical (TOPICAL)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2019'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 21:59:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 21:59:32
Data point term sent to Coder	System	13 Sep 2020 21:59:14
User entered 'sumatriptan'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'migraine'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '100'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'as needed (PRN)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2015'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
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)	26 Sep 2020 17:45:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 17:45:49
Data point term sent to Coder	System	26 Sep 2020 17:44:49
User entered 'tylenol'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'headache'	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '325'	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'twice daily (BID)'	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '12 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '12 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '2'	System	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '804 (804)'	System	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
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)	29 Oct 2020 21:24:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:24:44
Data point term sent to Coder	System	29 Oct 2020 21:23:37
User entered 'tylenol'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User closed query 'Per DM CLR: Please note there is no 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 AE eCRF.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please note there is no 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 AE eCRF.' answered with 'reported in ed diary, no seprate AE required' (Site from DM).	(u) (4), (b) (6)	26 Jan 2021 06:36:19
Query 'Per DM CLR: Please note there is no 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 AE eCRF.'	Dhwani Shah (b) (4)	20 Jan 2021 00:39:45
User opened query 'Per DM CLR: Please note there is no 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 AE eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 09:24:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'injection site pain'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '650'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'once (ONCE)'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '23 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '23 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:35:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:38:13
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.'	Dhwani Shah (b) (4)	01 Feb 2021 13:54:31
answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Dhwani Shah (b) (4)	01 Feb 2021 13:54:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	Dhwani Shah (b) (4)	01 Feb 2021 13:54:23
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 09:25:39
	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4)	18 Nov 2020 17:36:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:27:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:27:54
Data point term sent to Coder	System	16 Nov 2020 22:26:44
User entered 'ACYCLOVIR'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4) (u) (4), (u) (6)	21 Jan 2021 10:51:34
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' answered with 'updated AE' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 00:42:08
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 09:26:31
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'SHINGLES'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '800'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'FIVE TIMES A DAY'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '28 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '07 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User closed query 'Per DM CLR: this Con Med was added on 14 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 09:40:48
Query 'Per DM CLR: this Con Med was added on 14 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'pt is out from study and can not varify with patient ! Can not add AE without varifying with patient. reason is unknown ' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 14:02:13
User opened query 'Per DM CLR: this Con Med was added on 14 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 09:27:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:02:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:02:53
Data point term sent to Coder	System	16 Nov 2020 22:29:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

1466 of 1723

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'PROGESTERONE CAPS'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User closed query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 09:43:57
Query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	01 Feb 2021 14:00:56
User opened query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 05:25:39
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'POST Menopause syndrome'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '100'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'once daily (QD)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '14 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'l'	System	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '804 (804)'	System	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:11:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:11:54
Data point term sent to Coder	System	16 Nov 2020 22:30:50
User entered 'lidocaine 2% Cream'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'shingles'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'applicator'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'as needed (PRN)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'Topical (TOPICAL)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '30 Sep 2020'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:36:08
User entered '05 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User closed query 'Please update ConMed eCRF with additional ConMeds noted in source: Influenza Vaccine, 30OCT2020, Inj., IM, Flu Prophylaxis. Vitamin B12, start = UNK2019, 5000mcg, PO, QD, nutritional supplement. ' (Site from CRA).	(b) (4)	23 Nov 2020 18:17:02
Query 'Please update ConMed eCRF with additional ConMeds noted in source: Influenza Vaccine, 30OCT2020, Inj., IM, Flu Prophylaxis. Vitamin B12, start = UNK2019, 5000mcg, PO, QD, nutritional supplement. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	20 Nov 2020 17:26:47
User opened query 'Please update ConMed eCRF with additional ConMeds noted in source: Influenza Vaccine, 30OCT2020, Inj., IM, Flu Prophylaxis. Vitamin B12, start = UNK2019, 5000mcg, PO, QD, nutritional supplement. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:38:50
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 17:30:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 17:30:07
Data point term sent to Coder	System	20 Nov 2020 17:28:58
User entered 'influenza vaccine'	Dhwani Shah (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'flu prophylaxis'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:36:08
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Jan 2021 00:43:05
User entered '0.5' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Jan 2021 00:43:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:50:39
User entered '1'	Dhwani Shah (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:36:09
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Jan 2021 00:43:05
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Dhwani Shah (b) (4)	20 Jan 2021 00:43:05
	(b) (4), (b) (6)	16 Dec 2020 15:50:39
User entered 'Other (OTHER)'	Dhwani Shah (b) (4)	20 Nov 2020 17:28:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:36:12
DataPoint Un-verified.	Dhwani Shah (b) (4)	20 Jan 2021 00:43:05
User entered empty; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	20 Jan 2021 00:43:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:50:39
User entered 'injection'	Dhwani Shah (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'once (ONCE)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'Intramuscular (INTRAMUSCULAR)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered '30 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered '0'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered '30 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered empty.	System	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 17:46:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 17:46:01
Data point term sent to Coder	System	20 Nov 2020 17:28:58
User entered 'vitamin B12'	Dhwani Shah (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	02 Feb 2021 18:36:31
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 10:36:04
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 00:42:45
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 00:42:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	20 Jan 2021 00:42:40
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 09:33:16
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:50:39
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'nutritional supplement'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered '5000'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'ug (ug)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'once daily (QD)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'un UNK 2019'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered '0'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:50:39
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered 'I'	System	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:20:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '804 (804)'	System	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:20:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:22
User closed query 'Please confirm response and update with procedures performed per medical records obtained: CT of Abdomen with Contrast on 05Nov2020, Diagnostic Laparoscopy, Peritoneal Wash on 04Nov2020. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:47:18
Query 'Please confirm response and update with procedures performed per medical records obtained: CT of Abdomen with Contrast on 05Nov2020, Diagnostic Laparoscopy, Peritoneal Wash on 04Nov2020. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:28:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:28:32
User opened query 'Please confirm response and update with procedures performed per medical records obtained: CT of Abdomen with Contrast on 05Nov2020, Diagnostic Laparoscopy, Peritoneal Wash on 04Nov2020. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:01:32
User closed query 'Please confirm response. This page will need to be updated with procedures related to subject's cancer diagnosis upon receipt of medical records. Please ensure that all procedures are documented on Concomitant Procedures eCRF. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 22:05:58
Query 'Please confirm response. This page will need to be updated with procedures related to subject's cancer diagnosis upon receipt of medical records. Please ensure that all procedures are documented on Concomitant Procedures eCRF. ' answered with 'site still waiting for medical records, will updated as soon as receive medical records' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 22:31:53

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:20:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User opened query 'Please confirm response. This page will need to be updated with procedures related to subject's cancer diagnosis upon receipt of medical records. Please ensure that all procedures are documented on Concomitant Procedures eCRF. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:40:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:53:08

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:20:26

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered '05 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:29:21

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:20:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered 'CT OF ABDOMEN WITH CONTRAST'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:29:21

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered 'Adverse Event (AE)'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:29:21

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:20:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered empty.	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:29:21

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:20:26

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered '04 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:29:39

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:20:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered 'PERITONEAL WASH'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:29:39

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered 'Adverse Event (AE)'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:29:39

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:20:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered empty.	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:29:39

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:20:26

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered '04 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:30:06

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:20:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered 'DIAGNOSTIC LAPAROSCOPY'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:30:06

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered 'Adverse Event (AE)'	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:30:06

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:20:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Feb 2021 18:47:42
User entered empty.	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:30:06

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:20:26

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:31:08
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User entered '06 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	10 Mar 2021 18:00:15

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:20:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:31:08
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User entered 'colorectal cytology'	(b) (4) Dhwani Shah (b) (4) (b) (4)	10 Mar 2021 18:00:15

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:20:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:31:08
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User entered 'Adverse Event (AE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	10 Mar 2021 18:00:15

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:20:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:31:08
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	10 Mar 2021 18:00:15

US3562157

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:26

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:47:59
User entered '2 Dec 2020'	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 15:59:22

US3562157

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:26

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:47:59
User entered 'SAE (specify) (SAE)'	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 15:59:22

US3562157

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:38
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:02
User closed query 'Per CDM: Per sponsor review, please update specify field to include onlySAE, number sign, and number. (i.e. SAE #2).' (Site from DM).	(b) (4) (u) (4), (u) (6)	04 Mar 2021 09:47:23
Query 'Per CDM: Per sponsor review, please update specify field to include onlySAE, number sign, and number. (i.e. SAE #2).' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	02 Mar 2021 20:11:59
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	02 Mar 2021 20:11:53
Signature has been broken.	Dhwani Shah (b) (4) (b) (4)	02 Mar 2021 20:11:53
User entered 'SAE # 2' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	02 Mar 2021 20:11:53
User opened query 'Per CDM: Per sponsor review, please update specify field to include onlySAE, number sign, and number. (i.e. SAE #2).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 20:09:11
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(u) (4), (u) (6)	16 Dec 2020 15:47:59
User entered 'Dx of colon cancer, Pt is on chemo therapy and discontinue from study'	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 15:59:22

US3562157

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:26

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:47:59
User entered empty.	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 15:59:22

US3562157

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:26

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:47:59
User entered empty.	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 15:59:22

US3562157

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:26

Date of death (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:47:59
User entered empty.	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 15:59:22

US3562157

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:26

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	16 Dec 2020 15:47:59
User entered empty.	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 15:59:22

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '8'	System	18 Mar 2021 14:18:34
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
	(b) (4)	
User entered '7'	System	10 Feb 2021 15:35:02
User entered '6'	System	04 Feb 2021 14:49:10
User entered '5'	System	03 Feb 2021 15:39:06
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '8'	System	18 Mar 2021 14:18:34
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
	(b) (4)	
User entered '7'	System	10 Feb 2021 15:35:02
User entered '6'	System	04 Feb 2021 14:49:10
User entered '5'	System	03 Feb 2021 15:39:06
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:20:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
User entered '06/Nov/2020 22:58'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '8'	System	18 Mar 2021 14:18:34
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User entered '7'	System	10 Feb 2021 15:35:02
User entered '6'	System	04 Feb 2021 14:49:10
User entered '5'	System	03 Feb 2021 15:39:06
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:20:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
User entered '10/Nov/2020 14:25'	System	10 Nov 2020 14:25:40

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:56:29
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 14:25:40

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '8'	System	18 Mar 2021 14:18:34
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User entered '7'	System	10 Feb 2021 15:35:02
User entered '6'	System	04 Feb 2021 14:49:10
User entered '5'	System	03 Feb 2021 15:39:06
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:20:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
User entered '11/Nov/2020 19:56'	System	11 Nov 2020 19:56:42

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:53:13
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 19:56:42

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '8'	System	18 Mar 2021 14:18:34
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User entered '7'	System	10 Feb 2021 15:35:02
User entered '6'	System	04 Feb 2021 14:49:10
User entered '5'	System	03 Feb 2021 15:39:06
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:20:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
User entered '12/Nov/2020 15:53'	System	12 Nov 2020 15:53:33

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
Reviewed for Safety.	(b) (4) (u) (4), (u) (6)	03 Feb 2021 15:38:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 15:53:33

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '8'	System	18 Mar 2021 14:18:34
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User entered '7'	System	10 Feb 2021 15:35:02
User entered '6'	System	04 Feb 2021 14:49:10
User entered '5'	System	03 Feb 2021 15:39:06
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:20:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:32:34
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User entered '03/Feb/2021 10:39'	(b) (4) System	03 Feb 2021 15:39:06

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:32:36
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
Reviewed for Safety.	(b) (4)	
	(u) (4), (b) (6)	04 Feb 2021 14:48:58
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 15:39:06

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '8'	System	18 Mar 2021 14:18:34
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
	(b) (4)	
User entered '7'	System	10 Feb 2021 15:35:02
User entered '6'	System	04 Feb 2021 14:49:10
User entered '5'	System	03 Feb 2021 15:39:06
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:20:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:32:46
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User entered '04/Feb/2021 14:49'	(b) (4) System	04 Feb 2021 14:49:10

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:32:48
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:35:11
User entered 'I'	(b) (4), (b) (6)	04 Feb 2021 14:49:10

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '8'	System	18 Mar 2021 14:18:34
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User entered '7'	System	10 Feb 2021 15:35:02
User entered '6'	System	04 Feb 2021 14:49:10
User entered '5'	System	03 Feb 2021 15:39:06
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:20:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:32:58
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
User entered '10/Feb/2021 10:35'	(b) (4) System	10 Feb 2021 15:35:02

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:33:01
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:35:11
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 15:35:02

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
User entered '8'	System	18 Mar 2021 14:18:34
User signature succeeded.	Joseph Davis (b) (4)	23 Feb 2021 14:58:05
	(b) (4)	
User entered '7'	System	10 Feb 2021 15:35:02
User entered '6'	System	04 Feb 2021 14:49:10
User entered '5'	System	03 Feb 2021 15:39:06
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:20:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:27:43
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User entered '18/Mar/2021 10:18'	(b) (4) System	18 Mar 2021 14:18:34

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:20:26

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 19:25:47
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:27:45
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:36:42
User entered 'l'	(b) (4) (u) (4), (u) (6)	18 Mar 2021 14:18:34