

US3562230 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:16:59

All time stamps listed in this document are displayed in GMT

US3562230

Form: Participant Creation

Data signed: (b) (4) 24 Mar 2021 18:37:08

Generated On: 10 Jun 2021 08:16:59

Participant ID

US3562230

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

US3562230

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 16:39:10

Generated On: 10 Jun 2021 08:16:59

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3562230

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

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

US3562230

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Date of Informed Consent (<i>dd MMM yyyy</i>)	15 OCT 2020
Month and Year of Informed Consent (derived)	OCT 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

US3562230

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3562230

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Were any significant conditions reported?

Yes ☒

No ☐

US3562230

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Condition	INSOMNIA
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)	

US3562230

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

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

US3562230

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Mar 2021 16:39:12

Generated On: 10 Jun 2021 08:16:59

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	12:39 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 12:39
Height (xxx.x)	69.5 in
Weight (xxx.x)	377 lb
BMI (xxx.x)	54.98974 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)	

US3562230

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3562230

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

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

US3562230

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

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

US3562230

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 16:39:17

Generated On: 10 Jun 2021 08:16:59

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3562230

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 10 Mar 2021 16:39:16

Generated On: 10 Jun 2021 08:16:59

What was the date of randomization? (dd MMM yyyy) 15 OCT 2020

What was the participant's randomization number? 147042

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 ☒

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 10 Mar 2021 16:39:17

Generated On: 10 Jun 2021 08:16:59

Height	ND - Not Done
Weight	ND - Not Done

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 10 Mar 2021 16:39:17

Generated On: 10 Jun 2021 08:16:59

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)	15 OCT 2020
Time of assessment (00:00-23:59)	12:39 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 12:39
Temperature (xxx.x)	98.1 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)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Mar 2021 16:39:17

Generated On: 10 Jun 2021 08:16:59

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)	15 OCT 2020
Time of assessment (00:00-23:59)	14:26 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 14:26
Temperature (xxx.x)	99.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG

US3562230

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 10 Mar 2021 16:39:15

Generated On: 10 Jun 2021 08:16:59

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.

US3562230

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 10 Mar 2021 16:39:14

Generated On: 10 Jun 2021 08:16:59

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) 15 OCT 2020

What was the treatment time? (00:00-23:59) 13:51 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 13:51

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

US3562230

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Mar 2021 16:39:15

Generated On: 10 Jun 2021 08:16:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

13:24 (24 HR)

Collection date and time (derived)

15 OCT 2020 13:24

US3562230

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Mar 2021 16:39:14

Generated On: 10 Jun 2021 08:16:59

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:30	15 OCT 2020 13:30
Nasopharyngeal Swab 2	No		

US3562230

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:39:14

Generated On: 10 Jun 2021 08:16:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 14:27

PC Open Date & Time

15 OCT 2020 14:11

PC Close Date & Time

15 OCT 2020 16:41

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °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 OCT 2020 20:29
PC Open Date & Time	15 OCT 2020 17:36
PC Close Date & Time	16 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:59

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 23:31

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 22:12

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:59

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

19 OCT 2020 08:46

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 11:14

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:59

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

97.7 °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

21 OCT 2020 07:25

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 05:49

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

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

15 OCT 2020 14:28

PC Open Date & Time

15 OCT 2020 14:11

PC Close Date & Time

15 OCT 2020 16:41

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

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

15 OCT 2020 20:29

PC Open Date & Time

15 OCT 2020 17:36

PC Close Date & Time

16 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:59

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

16 OCT 2020 23:31

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:59

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

17 OCT 2020 22:13

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:59

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

19 OCT 2020 08:46

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:59

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

20 OCT 2020 11:15

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:59

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

21 OCT 2020 07:25

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:59

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

22 OCT 2020 05:49

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

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 ☐

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 14:29
PC Open Date & Time	15 OCT 2020 14:11
PC Close Date & Time	15 OCT 2020 16:41

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

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 ☐

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 20:30
PC Open Date & Time	15 OCT 2020 17:36
PC Close Date & Time	16 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

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)

43 of 940

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

Yes ☐	
PC Time stamp	16 OCT 2020 23:32
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

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)

45 of 940

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

Yes ☐	
PC Time stamp	17 OCT 2020 22:13
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

47 of 940

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

Yes ☐	
PC Time stamp	19 OCT 2020 08:46
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

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

49 of 940

EAB) (1725)

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

Yes ☐	
PC Time stamp	20 OCT 2020 11:15
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

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

EAB) (1725)

51 of 940

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

Yes ☐	
PC Time stamp	21 OCT 2020 07:26
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

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)

53 of 940

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

Yes ☐	
PC Time stamp	22 OCT 2020 05:50
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3562230

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

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

US3562230

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562230

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562230

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562230

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562230

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562230

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 16:39:31

Generated On: 10 Jun 2021 08:16:59

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 10 Mar 2021 16:39:31

Generated On: 10 Jun 2021 08:16:59

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Mar 2021 16:39:31

Generated On: 10 Jun 2021 08:16:59

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3562230

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Mar 2021 16:39:31

Generated On: 10 Jun 2021 08:16:59

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.

US3562230

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 10 Mar 2021 16:39:27

Generated On: 10 Jun 2021 08:16:59

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 PT DISCONTINUE FROM STUDY DUE TO SAE

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3562230

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Mar 2021 16:39:30

Generated On: 10 Jun 2021 08:16:59

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3562230

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Mar 2021 16:39:23

Generated On: 10 Jun 2021 08:16:59

Collection date (dd MMM yyyy)

Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3562230

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:39:26

Generated On: 10 Jun 2021 08:16:59

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3562230

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Mar 2021 18:37:08

Generated On: 10 Jun 2021 08:16:59

AEID

Adverse event

DIARRHEA

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)

22 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

70 of 940

EAB) (1725)

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Mar 2021 18:37:08

Generated On: 10 Jun 2021 08:16:59

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

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Mar 2021 18:37:08

Generated On: 10 Jun 2021 08:16:59

AEID	USA-US071-2020-MRNA-1273-P30 1000003
Adverse event	LIVER ABCESS
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	07 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)	17 NOV 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	True
Hospital Admission Date (dd MMM yyyy)	07 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	17 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

72 of 940

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Mar 2021 18:37:08

Generated On: 10 Jun 2021 08:16:59

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☒ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PT DEVELOPED SYMPTOMS LIKE ABDOMINAL PAIN AND DARK URINE. WENT TO ER ON 11/7/2020 AND GOT ADMITTED. WE WILL PROVIDE MORE INFO ONCE SITE RECEIVE MEDICAL RECORDS

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Mar 2021 18:37:08

Generated On: 10 Jun 2021 08:16:59

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)	0

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Mar 2021 18:37:08

Generated On: 10 Jun 2021 08:16:59

AEID	
Adverse event	CHILLS/FEVER
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)	01 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)	07 NOV 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

75 of 940

EAB) (1725)

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Mar 2021 18:37:08

Generated On: 10 Jun 2021 08:16:59

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

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Mar 2021 18:37:08

Generated On: 10 Jun 2021 08:16:59

AEID

Adverse event

ABDOMINAL 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)

01 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)

07 NOV 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

77 of 940

EAB) (1725)

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Mar 2021 18:37:08

Generated On: 10 Jun 2021 08:16:59

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

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

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

Yes ☒

No ☐

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

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

80 of 940

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

	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	☐

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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)

82 of 940

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

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

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication BLOOD CLOTS PROPHYLAXIS

Dose per administration 5000

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

If dose unit is Other, specify UNITS

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 EVERY 8 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

84 of 940

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 NOV 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	☐

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication LIVER ABCESS

Dose per administration 250

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

EVRY 6 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

86 of 940

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	17 NOV 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	☐

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

Name of Medication ONDANSETRON

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PROPHYLAXIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

88 of 940

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	17 NOV 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	☐

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

Name of Medication HYDRALAZINE

Prophylaxis Yes ☒
No ☐

Indication BLOOD PRESSURE
PROPHYLAXIS

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

EVERY 6 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

90 of 940

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 NOV 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	☐

US3562230

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3562230

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Date of dosing discontinuation (dd MMM yyyy) 20 NOV 2020

Primary reason for dosing discontinuation

AE (specify)	☐
SAE (specify)	☒
Death	☐
Lost To Follow-up	☐
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Due to SARS-COV-2	☐
Other	☐

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

AE # 2

US3562230

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 10 Mar 2021 16:39:09

Generated On: 10 Jun 2021 08:16:59

Date of study discontinuation/completion (dd MMM yyyy) 20 NOV 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

DOE NOT WANT TO CONTINUE WITH STUDY DUE TO RECENT HOSPITALIZED

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	☐

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

SAEID	USA-US071-2020-MRNA-1273-P301000003
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)	5

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

SAEID	USA-US071-2020-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	10/NOV/2020 11:52
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

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

SAEID	USA-US071-2020-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	23/NOV/2020 17:48
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

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

SAEID	USA-US071-2020-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	04/DEC/2020 13:46
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

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

SAEID	USA-US071-2020-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	15/DEC/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

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 24 Mar 2021 18:37:09

Generated On: 10 Jun 2021 08:16:59

SAEID	USA-US071-2020-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	16/DEC/2020 07:55
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

US3562230 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3562230

Form: Participant Creation

Generated On: 10 Jun 2021 08:16:59

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:12:46
User entered 'US3562230'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 20:08:29

US3562230

Form: Participant Creation

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:05:58

US3562230

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '15 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 20:08:31

US3562230

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

[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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:05:58

US3562230

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'SCRN'	System	15 Oct 2020 21:05:58

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered (b) (6) 1975'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 20:08:32

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '45'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'YEARS'	System	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '45'	System	15 Oct 2020 21:06:49

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Male (M)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Dhwani Shah (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'mexican american'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:26

US3562230

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:49

US3562230

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'Oct 2020'	System	15 Oct 2020 21:06:49

US3562230

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '2020'	System	15 Oct 2020 21:06:49

US3562230

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Amendment 4 (4)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:49

US3562230

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:49

US3562230

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:49

US3562230

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:49

US3562230

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:49

US3562230

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 20:08:31

US3562230

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'I'	System	15 Oct 2020 21:06:54

US3562230

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:06:54

US3562230

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:16:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:42:39

US3562230

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 17:44:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 17:44:23
Data point term sent to Coder	System	19 Oct 2020 17:43:42
User entered 'INSOMNIA'	Dhwani Shah (b) (4)	19 Oct 2020 17:42:52
	(b) (4)	

US3562230

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'UN UNK 2015'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:42:52

US3562230

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:42:52

US3562230

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:42:52

US3562230

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:42:52

US3562230

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:42:52

US3562230

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'Jan 2015'	System	19 Oct 2020 17:42:52

US3562230

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '2015'	System	19 Oct 2020 17:42:52

US3562230

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	19 Oct 2020 17:42:52

US3562230

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	19 Oct 2020 17:42:52

US3562230

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Oct 2020 17:44:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 17:44:23
Data point term sent to Coder	System	19 Oct 2020 17:43:42
User entered 'OBESITY'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:43:02

US3562230

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'UN UNK 1995'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:43:02

US3562230

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:43:02

US3562230

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:43:02

US3562230

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:43:02

US3562230

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 17:43:02

US3562230

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'Jan 1995'	System	19 Oct 2020 17:43:02

US3562230

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '1995'	System	19 Oct 2020 17:43:02

US3562230

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	19 Oct 2020 17:43:02

US3562230

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	19 Oct 2020 17:43:02

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '12:39'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '15 Oct 2020 12:39'	System	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '69.5' in	(b) (4)	
	Dhwani Shah (b) (4)	18 Oct 2020 18:09:14
DataPoint set to visible.	(b) (4)	
	System	15 Oct 2020 21:06:54

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '377' lb	(b) (4) Dhwani Shah (b) (4)	18 Oct 2020 18:09:14
DataPoint set to visible.	(b) (4) System	15 Oct 2020 21:06:54

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '54.98974'	System	18 Oct 2020 18:09:14
DataPoint set to visible.	System	15 Oct 2020 21:06:54

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'kg/m2'	System	18 Oct 2020 18:09:14
DataPoint set to visible.	System	15 Oct 2020 21:06:54

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'bpm'	System	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'breaths/min'	System	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'mmHg'	System	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'mmHg'	System	18 Oct 2020 18:09:14

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:22

US3562230

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:09:22

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

[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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

[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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

[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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

[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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:18

US3562230

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:07:47

US3562230

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:07:47

US3562230

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

[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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:07:47

US3562230

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'VISIT1'	System	15 Oct 2020 21:07:47

US3562230

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '15 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 20:18:36

US3562230

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '147042'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 20:18:36

US3562230

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 20:18:36

US3562230

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:35

US3562230

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:35

US3562230

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:35

US3562230

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:35

US3562230

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:10:35

US3562230

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4)	18 Oct 2020 18:10:35
DataPoint set to visible.	(b) (4) System	15 Oct 2020 21:06:49

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '12:39'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '15 Oct 2020 12:39'	System	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '98.1' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '69'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'bpm'	System	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'breaths/min'	System	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '150'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'mmHg'	System	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '90'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'mmHg'	System	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '14:26'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '15 Oct 2020 14:26'	System	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '99.8' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '62'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'bpm'	System	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'breaths/min'	System	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User closed query 'Per CDM: Systolic Blood Pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:37:23
Query 'Per CDM: Systolic Blood Pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate. ' answered with 'confirmed NCS' (Site from DM).	Dhwani Shah (b) (4)	05 Feb 2021 23:52:07
User opened query 'Per CDM: Systolic Blood Pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 13:01:30
User entered '159'	Dhwani Shah (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'mmHg'	System	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '102'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'mmHg'	System	18 Oct 2020 18:11:57

US3562230

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:20

US3562230

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:20

US3562230

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:07:26

US3562230

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:07:26

US3562230

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:07:26

US3562230

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 21:07:26

US3562230

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:07:26

US3562230

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '13:51'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:07:26

US3562230

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '15 Oct 2020 13:51'	System	15 Oct 2020 21:07:26

US3562230

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Left Arm (LEFT ARM)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:07:26

US3562230

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'ONCE'	System	15 Oct 2020 21:07:26

US3562230

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 21:07:26

US3562230

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:39

US3562230

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:39

US3562230

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '13:24'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:39

US3562230

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '15 Oct 2020 13:24'	System	18 Oct 2020 18:12:39

US3562230

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:16:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:54

US3562230

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:54

US3562230

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:54

US3562230

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered '13:30'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:54

US3562230

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '15 Oct 2020 13:30'	System	18 Oct 2020 18:12:54

US3562230

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:54

US3562230

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:54

US3562230

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:12:54

US3562230

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	18 Oct 2020 18:12:54

US3562230

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 21:07:31

US3562230

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:16:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'I'	System	15 Oct 2020 21:07:31

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:27:38', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '452bfc29-16f5-4a85-907e-18619b49c540' User entered 'Yes (Y)'	System	15 Oct 2020 21:28:02
	System	15 Oct 2020 21:28:02

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:27:46', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '452bfc29-16f5-4a85-907e-18619b49c540' User entered '99.8'	System	15 Oct 2020 21:28:02
	System	15 Oct 2020 21:28:02

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:27:52', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '452bfc29-16f5-4a85-907e-18619b49c540'	System	15 Oct 2020 21:28:02
User entered 'No (N)'	System	15 Oct 2020 21:28:02

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:27:58', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '452bfc29-16f5-4a85-907e-18619b49c540' User entered '15 Oct 2020 14:27'	System	15 Oct 2020 21:28:02
	System	15 Oct 2020 21:28:02

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '15 Oct 2020 14:11'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '15 Oct 2020 16:41'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:28:54', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'dc9241f1-a30a-4e0c-a7b5-904deff1675e' User entered 'Yes (Y)'	System	16 Oct 2020 03:29:14
	System	16 Oct 2020 03:29:14

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:29:01', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'dc9241f1-a30a-4e0c-a7b5-904deff1675e' User entered '97.6'	System	16 Oct 2020 03:29:14
	System	16 Oct 2020 03:29:14

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:29:05', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'dc9241f1-a30a-4e0c-a7b5-904deff1675e' User entered 'No (N)'	System	16 Oct 2020 03:29:14
	System	16 Oct 2020 03:29:14

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:29:10', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'dc9241f1-a30a-4e0c-a7b5-904deff1675e' User entered '15 Oct 2020 20:29'	System	16 Oct 2020 03:29:14
	System	16 Oct 2020 03:29:14

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '15 Oct 2020 17:36'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 2'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:02', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'ffcc0efc-21d4-46a0-82db-4054dd640432'	System	17 Oct 2020 06:31:25
User entered 'Yes (Y)'	System	17 Oct 2020 06:31:25

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:12', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'ffcc0efc-21d4-46a0-82db-4054dd640432'	System	17 Oct 2020 06:31:25
User entered '96.8'	System	17 Oct 2020 06:31:25

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:18', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'ffcc0efc-21d4-46a0-82db-4054dd640432'	System	17 Oct 2020 06:31:25
User entered 'No (N)'	System	17 Oct 2020 06:31:25

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:23', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'ffcc0efc-21d4-46a0-82db-4054dd640432'	System	17 Oct 2020 06:31:25
User entered '16 Oct 2020 23:31'	System	17 Oct 2020 06:31:25

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 3'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:12:28', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '65dbeca1-83f0-4c5b-89cb-5f75c6d6a736' User entered 'Yes (Y)'	System	18 Oct 2020 05:12:48
	System	18 Oct 2020 05:12:48

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:12:38', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '65dbeca1-83f0-4c5b-89cb-5f75c6d6a736' User entered '98.4'	System	18 Oct 2020 05:12:48
	System	18 Oct 2020 05:12:48

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:12:42', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '65dbeca1-83f0-4c5b-89cb-5f75c6d6a736'	System	18 Oct 2020 05:12:48
User entered 'No (N)'	System	18 Oct 2020 05:12:48

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:12:46', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '65dbeca1-83f0-4c5b-89cb-5f75c6d6a736' User entered '17 Oct 2020 22:12'	System	18 Oct 2020 05:12:48
	System	18 Oct 2020 05:12:48

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 4'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:45:53', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '42c48e9a-522c-43b1-9a96-dbb918e1c14d' User entered 'Yes (Y)'	System	19 Oct 2020 15:46:17
	System	19 Oct 2020 15:46:17

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:03', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '42c48e9a-522c-43b1-9a96-dbb918e1c14d' User entered '97.6'	System	19 Oct 2020 15:46:17
	System	19 Oct 2020 15:46:17

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:07', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '42c48e9a-522c-43b1-9a96-dbb918e1c14d'	System	19 Oct 2020 15:46:17
User entered 'No (N)'	System	19 Oct 2020 15:46:17

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:11', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '42c48e9a-522c-43b1-9a96-dbb918e1c14d' User entered '19 Oct 2020 08:46'	System	19 Oct 2020 15:46:17
	System	19 Oct 2020 15:46:17

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 5'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:14:35', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'aff3d407-8572-4f71-8a9e-3ae1bdcf996f' User entered 'Yes (Y)'	System	20 Oct 2020 18:14:49
	System	20 Oct 2020 18:14:49

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:14:42', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'aff3d407-8572-4f71-8a9e-3ae1bdcf996f' User entered '98.2'	System	20 Oct 2020 18:14:49
	System	20 Oct 2020 18:14:49

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:14:45', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'aff3d407-8572-4f71-8a9e-3ae1bdcf996f' User entered 'No (N)'	System	20 Oct 2020 18:14:49
	System	20 Oct 2020 18:14:49

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:14:47', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'aff3d407-8572-4f71-8a9e-3ae1bdcf996f' User entered '20 Oct 2020 11:14'	System	20 Oct 2020 18:14:49
	System	20 Oct 2020 18:14:49

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 6'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:08', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '97a04aa0-01c7-4c59-ac81-1f0cf28266bb' User entered 'Yes (Y)'	System	21 Oct 2020 14:25:29
	System	21 Oct 2020 14:25:29

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:15', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '97a04aa0-01c7-4c59-ac81-1f0cf28266bb' User entered '97.7'	System	21 Oct 2020 14:25:29
	System	21 Oct 2020 14:25:29

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:18', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '97a04aa0-01c7-4c59-ac81-1f0cf28266bb'	System	21 Oct 2020 14:25:29
User entered 'No (N)'	System	21 Oct 2020 14:25:29

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:21', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '97a04aa0-01c7-4c59-ac81-1f0cf28266bb' User entered '21 Oct 2020 07:25'	System	21 Oct 2020 14:25:29
	System	21 Oct 2020 14:25:29

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 7'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:09', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2a15e73b-9a2d-47c2-984d-c24e21138845' User entered 'Yes (Y)'	System	22 Oct 2020 12:49:23
	System	22 Oct 2020 12:49:23

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:15', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2a15e73b-9a2d-47c2-984d-c24e21138845' User entered '98.1'	System	22 Oct 2020 12:49:23
	System	22 Oct 2020 12:49:23

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:18', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2a15e73b-9a2d-47c2-984d-c24e21138845'	System	22 Oct 2020 12:49:23
User entered 'No (N)'	System	22 Oct 2020 12:49:23

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:21', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2a15e73b-9a2d-47c2-984d-c24e21138845' User entered '22 Oct 2020 05:49'	System	22 Oct 2020 12:49:23
	System	22 Oct 2020 12:49:23

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:28:18', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c9dea16c-09e0-4298-9f18-1da28084bed5'	System	15 Oct 2020 21:28:56
User entered 'None (1)'	System	15 Oct 2020 21:28:56

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:28:29', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c9dea16c-09e0-4298-9f18-1da28084bed5' User entered 'No (N)'	System	15 Oct 2020 21:28:56
	System	15 Oct 2020 21:28:56

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:28:38', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c9dea16c-09e0-4298-9f18-1da28084bed5' User entered 'No (N)'	System	15 Oct 2020 21:28:56
	System	15 Oct 2020 21:28:56

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:28:46', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c9dea16c-09e0-4298-9f18-1da28084bed5'	System	15 Oct 2020 21:28:56
User entered 'None (1)'	System	15 Oct 2020 21:28:56

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:28:50', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c9dea16c-09e0-4298-9f18-1da28084bed5' User entered '15 Oct 2020 14:28'	System	15 Oct 2020 21:28:56
	System	15 Oct 2020 21:28:56

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '15 Oct 2020 14:11'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '15 Oct 2020 16:41'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:29:18', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'be1b060e-3fcf-4906-b09d-c97e925e9c9f' User entered 'None (1)'	System	16 Oct 2020 03:29:52
	System	16 Oct 2020 03:29:52

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:29:22', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'be1b060e-3fcf-4906-b09d-c97e925e9c9f' User entered 'No (N)'	System	16 Oct 2020 03:29:52
	System	16 Oct 2020 03:29:52

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:29:26', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'be1b060e-3fcf-4906-b09d-c97e925e9c9f' User entered 'No (N)'	System	16 Oct 2020 03:29:52
	System	16 Oct 2020 03:29:52

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:29:43', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'be1b060e-3fcf-4906-b09d-c97e925e9c9f' User entered 'None (1)'	System	16 Oct 2020 03:29:52
	System	16 Oct 2020 03:29:52

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:29:49', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'be1b060e-3fcf-4906-b09d-c97e925e9c9f' User entered '15 Oct 2020 20:29'	System	16 Oct 2020 03:29:52
	System	16 Oct 2020 03:29:52

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '15 Oct 2020 17:36'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 2'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:32', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e5a4d4b9-1c32-47cb-9d3f-7fd038c04fe2'	System	17 Oct 2020 06:31:51
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 06:31:51

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:36', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e5a4d4b9-1c32-47cb-9d3f-7fd038c04fe2'	System	17 Oct 2020 06:31:51
User entered 'No (N)'	System	17 Oct 2020 06:31:51

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:40', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e5a4d4b9-1c32-47cb-9d3f-7fd038c04fe2'	System	17 Oct 2020 06:31:51
User entered 'No (N)'	System	17 Oct 2020 06:31:51

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:45', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e5a4d4b9-1c32-47cb-9d3f-7fd038c04fe2'	System	17 Oct 2020 06:31:51
User entered 'None (1)'	System	17 Oct 2020 06:31:51

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:47', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e5a4d4b9-1c32-47cb-9d3f-7fd038c04fe2'	System	17 Oct 2020 06:31:51
User entered '16 Oct 2020 23:31'	System	17 Oct 2020 06:31:51

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 3'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:12:56', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'a908358a-2fd3-4e42-bbcc-6e177a9f12d2'	System	18 Oct 2020 05:13:16
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 05:13:16

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:12:59', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'a908358a-2fd3-4e42-bbcc-6e177a9f12d2'	System	18 Oct 2020 05:13:16
User entered 'No (N)'	System	18 Oct 2020 05:13:16

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:13:03', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'a908358a-2fd3-4e42-bbcc-6e177a9f12d2'	System	18 Oct 2020 05:13:16
User entered 'No (N)'	System	18 Oct 2020 05:13:16

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:13:07', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'a908358a-2fd3-4e42-bbcc-6e177a9f12d2'	System	18 Oct 2020 05:13:16
User entered 'None (1)'	System	18 Oct 2020 05:13:16

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:13:10', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'a908358a-2fd3-4e42-bbcc-6e177a9f12d2'	System	18 Oct 2020 05:13:16
User entered '17 Oct 2020 22:13'	System	18 Oct 2020 05:13:16

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 4'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:16', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c4b7d790-696a-4944-8313-e750d5a3cde4' User entered 'None (1)'	System	19 Oct 2020 15:46:28
	System	19 Oct 2020 15:46:28

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:18', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c4b7d790-696a-4944-8313-e750d5a3cde4' User entered 'No (N)'	System	19 Oct 2020 15:46:28
	System	19 Oct 2020 15:46:28

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:21', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c4b7d790-696a-4944-8313-e750d5a3cde4' User entered 'No (N)'	System	19 Oct 2020 15:46:28
	System	19 Oct 2020 15:46:28

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:24', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c4b7d790-696a-4944-8313-e750d5a3cde4' User entered 'None (1)'	System	19 Oct 2020 15:46:28
	System	19 Oct 2020 15:46:28

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:26', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c4b7d790-696a-4944-8313-e750d5a3cde4' User entered '19 Oct 2020 08:46'	System	19 Oct 2020 15:46:28
	System	19 Oct 2020 15:46:28

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 5'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:14:51', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'acc1c6b-8089-47d1-a7d7-5f91bcad71ff'	System	20 Oct 2020 18:15:02
User entered 'None (1)'	System	20 Oct 2020 18:15:02

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:14:53', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'acc1c6b-8089-47d1-a7d7-5f91bcad71ff'	System	20 Oct 2020 18:15:02
User entered 'No (N)'	System	20 Oct 2020 18:15:02

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:14:55', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'acc1c6b-8089-47d1-a7d7-5f91bcad71ff' User entered 'No (N)'	System	20 Oct 2020 18:15:02
	System	20 Oct 2020 18:15:02

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:14:58', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'acc1c6b-8089-47d1-a7d7-5f91bcad71ff'	System	20 Oct 2020 18:15:02
User entered 'None (1)'	System	20 Oct 2020 18:15:02

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:15:00', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'accclc6b-8089-47d1-a7d7-5f91bcad71ff' User entered '20 Oct 2020 11:15'	System	20 Oct 2020 18:15:02
	System	20 Oct 2020 18:15:02

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 6'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:25', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '912701af-199f-4695-99a7-3b73d6bbc318'	System	21 Oct 2020 14:25:39
User entered 'None (1)'	System	21 Oct 2020 14:25:39

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:28', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '912701af-199f-4695-99a7-3b73d6bbc318' User entered 'No (N)'	System	21 Oct 2020 14:25:39
	System	21 Oct 2020 14:25:39

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:31', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '912701af-199f-4695-99a7-3b73d6bbc318' User entered 'No (N)'	System	21 Oct 2020 14:25:39
	System	21 Oct 2020 14:25:39

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:33', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '912701af-199f-4695-99a7-3b73d6bbc318'	System	21 Oct 2020 14:25:39
User entered 'None (1)'	System	21 Oct 2020 14:25:39

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:36', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '912701af-199f-4695-99a7-3b73d6bbc318' User entered '21 Oct 2020 07:25'	System	21 Oct 2020 14:25:39
	System	21 Oct 2020 14:25:39

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 7'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:27', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '3170eb40-18c7-46a5-89d1-ca21eb097212'	System	22 Oct 2020 12:49:41
User entered 'None (1)'	System	22 Oct 2020 12:49:41

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:30', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '3170eb40-18c7-46a5-89d1-ca21eb097212' User entered 'No (N)'	System	22 Oct 2020 12:49:41
	System	22 Oct 2020 12:49:41

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:33', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '3170eb40-18c7-46a5-89d1-ca21eb097212' User entered 'No (N)'	System	22 Oct 2020 12:49:41
	System	22 Oct 2020 12:49:41

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:35', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '3170eb40-18c7-46a5-89d1-ca21eb097212'	System	22 Oct 2020 12:49:41
User entered 'None (1)'	System	22 Oct 2020 12:49:41

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:39', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '3170eb40-18c7-46a5-89d1-ca21eb097212' User entered '22 Oct 2020 05:49'	System	22 Oct 2020 12:49:41
	System	22 Oct 2020 12:49:41

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:28:56', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '045fea76-8984-4803-a316-86ace42dd940' User entered 'None (0)'	System	15 Oct 2020 21:29:27
	System	15 Oct 2020 21:29:27

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:28:59', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '045fea76-8984-4803-a316-86ace42dd940' User entered 'None (0)'	System	15 Oct 2020 21:29:27
	System	15 Oct 2020 21:29:27

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:29:04', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '045fea76-8984-4803-a316-86ace42dd940' User entered 'None (0)'	System	15 Oct 2020 21:29:27
	System	15 Oct 2020 21:29:27

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:29:10', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '045fea76-8984-4803-a316-86ace42dd940' User entered 'None (0)'	System	15 Oct 2020 21:29:27
	System	15 Oct 2020 21:29:27

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:29:14', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '045fea76-8984-4803-a316-86ace42dd940' User entered 'None (0)'	System	15 Oct 2020 21:29:27
	System	15 Oct 2020 21:29:27

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:29:17', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '045fea76-8984-4803-a316-86ace42dd940' User entered 'None (0)'	System	15 Oct 2020 21:29:27
	System	15 Oct 2020 21:29:27

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:29:21', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '045fea76-8984-4803-a316-86ace42dd940' User entered 'No (N)'	System	15 Oct 2020 21:29:27
	System	15 Oct 2020 21:29:27

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T14:29:24', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '045fea76-8984-4803-a316-86ace42dd940' User entered '15 Oct 2020 14:29'	System	15 Oct 2020 21:29:27
	System	15 Oct 2020 21:29:27

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '15 Oct 2020 14:11'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '15 Oct 2020 16:41'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:29:55', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '7985f39b-254d-4b51-a2bc-3a80816d6199' User entered 'None (0)'	System	16 Oct 2020 03:30:30
	System	16 Oct 2020 03:30:30

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:29:59', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '7985f39b-254d-4b51-a2bc-3a80816d6199' User entered 'None (0)'	System	16 Oct 2020 03:30:30
	System	16 Oct 2020 03:30:30

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:30:03', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '7985f39b-254d-4b51-a2bc-3a80816d6199' User entered 'None (0)'	System	16 Oct 2020 03:30:30
	System	16 Oct 2020 03:30:30

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:30:06', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '7985f39b-254d-4b51-a2bc-3a80816d6199' User entered 'None (0)'	System	16 Oct 2020 03:30:30
	System	16 Oct 2020 03:30:30

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:30:15', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '7985f39b-254d-4b51-a2bc-3a80816d6199' User entered 'None (0)'	System	16 Oct 2020 03:30:30
	System	16 Oct 2020 03:30:30

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:30:18', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '7985f39b-254d-4b51-a2bc-3a80816d6199' User entered 'None (0)'	System	16 Oct 2020 03:30:30
	System	16 Oct 2020 03:30:30

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:30:23', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '7985f39b-254d-4b51-a2bc-3a80816d6199'	System	16 Oct 2020 03:30:30
User entered 'No (N)'	System	16 Oct 2020 03:30:30

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-15T20:30:28', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '7985f39b-254d-4b51-a2bc-3a80816d6199' User entered '15 Oct 2020 20:30'	System	16 Oct 2020 03:30:30
	System	16 Oct 2020 03:30:30

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '15 Oct 2020 17:36'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 2'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:53', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '54c3e976-ce79-4f17-8de4-be793de22f6a' User entered 'None (0)'	System	17 Oct 2020 06:32:13
	System	17 Oct 2020 06:32:13

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:56', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '54c3e976-ce79-4f17-8de4-be793de22f6a' User entered 'None (0)'	System	17 Oct 2020 06:32:13
	System	17 Oct 2020 06:32:13

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:31:58', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '54c3e976-ce79-4f17-8de4-be793de22f6a' User entered 'None (0)'	System	17 Oct 2020 06:32:13
	System	17 Oct 2020 06:32:13

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:32:01', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '54c3e976-ce79-4f17-8de4-be793de22f6a' User entered 'None (0)'	System	17 Oct 2020 06:32:13
	System	17 Oct 2020 06:32:13

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:32:03', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '54c3e976-ce79-4f17-8de4-be793de22f6a' User entered 'None (0)'	System	17 Oct 2020 06:32:13
	System	17 Oct 2020 06:32:13

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:32:06', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '54c3e976-ce79-4f17-8de4-be793de22f6a' User entered 'None (0)'	System	17 Oct 2020 06:32:13
	System	17 Oct 2020 06:32:13

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:32:09', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '54c3e976-ce79-4f17-8de4-be793de22f6a' User entered 'No (N)'	System	17 Oct 2020 06:32:13
	System	17 Oct 2020 06:32:13

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-16T23:32:11', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '54c3e976-ce79-4f17-8de4-be793de22f6a' User entered '16 Oct 2020 23:32'	System	17 Oct 2020 06:32:13
	System	17 Oct 2020 06:32:13

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 3'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:13:15', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e368f7af-7828-4c0a-a1c9-c2f040d35b95' User entered 'None (0)'	System	18 Oct 2020 05:13:38
	System	18 Oct 2020 05:13:38

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:13:18', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e368f7af-7828-4c0a-a1c9-c2f040d35b95' User entered 'None (0)'	System	18 Oct 2020 05:13:38
	System	18 Oct 2020 05:13:38

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:13:21', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e368f7af-7828-4c0a-a1c9-c2f040d35b95' User entered 'None (0)'	System	18 Oct 2020 05:13:38
	System	18 Oct 2020 05:13:38

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:13:24', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e368f7af-7828-4c0a-a1c9-c2f040d35b95' User entered 'None (0)'	System	18 Oct 2020 05:13:38
	System	18 Oct 2020 05:13:38

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:13:26', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e368f7af-7828-4c0a-a1c9-c2f040d35b95' User entered 'None (0)'	System	18 Oct 2020 05:13:38
	System	18 Oct 2020 05:13:38

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:13:28', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e368f7af-7828-4c0a-a1c9-c2f040d35b95' User entered 'None (0)'	System	18 Oct 2020 05:13:38
	System	18 Oct 2020 05:13:38

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:13:32', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e368f7af-7828-4c0a-a1c9-c2f040d35b95'	System	18 Oct 2020 05:13:38
User entered 'No (N)'	System	18 Oct 2020 05:13:38

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-17T22:13:36', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'e368f7af-7828-4c0a-a1c9-c2f040d35b95' User entered '17 Oct 2020 22:13'	System	18 Oct 2020 05:13:38
	System	18 Oct 2020 05:13:38

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 4'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:31', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c5604744-cf95-4a87-b9ab-4ea087b1c28a' User entered 'None (0)'	System	19 Oct 2020 15:46:53
	System	19 Oct 2020 15:46:53

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:34', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c5604744-cf95-4a87-b9ab-4ea087b1c28a' User entered 'None (0)'	System	19 Oct 2020 15:46:53
	System	19 Oct 2020 15:46:53

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:36', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c5604744-cf95-4a87-b9ab-4ea087b1c28a' User entered 'None (0)'	System	19 Oct 2020 15:46:53
	System	19 Oct 2020 15:46:53

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:38', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c5604744-cf95-4a87-b9ab-4ea087b1c28a' User entered 'None (0)'	System	19 Oct 2020 15:46:53
	System	19 Oct 2020 15:46:53

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:40', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c5604744-cf95-4a87-b9ab-4ea087b1c28a' User entered 'None (0)'	System	19 Oct 2020 15:46:53
	System	19 Oct 2020 15:46:53

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:43', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c5604744-cf95-4a87-b9ab-4ea087b1c28a' User entered 'None (0)'	System	19 Oct 2020 15:46:53
	System	19 Oct 2020 15:46:53

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:45', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c5604744-cf95-4a87-b9ab-4ea087b1c28a' User entered 'No (N)'	System	19 Oct 2020 15:46:53
	System	19 Oct 2020 15:46:53

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-19T08:46:49', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: 'c5604744-cf95-4a87-b9ab-4ea087b1c28a' User entered '19 Oct 2020 08:46'	System	19 Oct 2020 15:46:53
	System	19 Oct 2020 15:46:53

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 5'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:15:05', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '5f1e8682-8c13-4a99-a8d9-f56387453b88' User entered 'None (0)'	System	20 Oct 2020 18:15:22
	System	20 Oct 2020 18:15:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:15:06', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '5f1e8682-8c13-4a99-a8d9-f56387453b88' User entered 'None (0)'	System	20 Oct 2020 18:15:22
	System	20 Oct 2020 18:15:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:15:08', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '5f1e8682-8c13-4a99-a8d9-f56387453b88' User entered 'None (0)'	System	20 Oct 2020 18:15:22
	System	20 Oct 2020 18:15:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:15:11', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '5f1e8682-8c13-4a99-a8d9-f56387453b88' User entered 'None (0)'	System	20 Oct 2020 18:15:22
	System	20 Oct 2020 18:15:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:15:13', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '5f1e8682-8c13-4a99-a8d9-f56387453b88' User entered 'None (0)'	System	20 Oct 2020 18:15:22
	System	20 Oct 2020 18:15:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:15:14', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '5f1e8682-8c13-4a99-a8d9-f56387453b88' User entered 'None (0)'	System	20 Oct 2020 18:15:22
	System	20 Oct 2020 18:15:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:15:17', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '5f1e8682-8c13-4a99-a8d9-f56387453b88'	System	20 Oct 2020 18:15:22
User entered 'No (N)'	System	20 Oct 2020 18:15:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-20T11:15:20', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '5f1e8682-8c13-4a99-a8d9-f56387453b88' User entered '20 Oct 2020 11:15'	System	20 Oct 2020 18:15:22
	System	20 Oct 2020 18:15:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 6'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:44', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '58e17727-b33b-4273-8db5-be2d4ff31be4' User entered 'None (0)'	System	21 Oct 2020 14:26:22
	System	21 Oct 2020 14:26:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:53', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '58e17727-b33b-4273-8db5-be2d4ff31be4' User entered 'None (0)'	System	21 Oct 2020 14:26:22
	System	21 Oct 2020 14:26:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:56', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '58e17727-b33b-4273-8db5-be2d4ff31be4' User entered 'None (0)'	System	21 Oct 2020 14:26:22
	System	21 Oct 2020 14:26:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:25:58', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '58e17727-b33b-4273-8db5-be2d4ff31be4' User entered 'None (0)'	System	21 Oct 2020 14:26:22
	System	21 Oct 2020 14:26:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:26:06', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '58e17727-b33b-4273-8db5-be2d4ff31be4'	System	21 Oct 2020 14:26:22
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Oct 2020 14:26:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:26:08', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '58e17727-b33b-4273-8db5-be2d4ff31be4' User entered 'None (0)'	System	21 Oct 2020 14:26:22
	System	21 Oct 2020 14:26:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:26:12', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '58e17727-b33b-4273-8db5-be2d4ff31be4' User entered 'No (N)'	System	21 Oct 2020 14:26:22
	System	21 Oct 2020 14:26:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-21T07:26:15', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '58e17727-b33b-4273-8db5-be2d4ff31be4' User entered '21 Oct 2020 07:26'	System	21 Oct 2020 14:26:22
	System	21 Oct 2020 14:26:22

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
Data entry locked.	System	15 Oct 2020 21:07:26
User entered 'Day 7'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:43', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2fa9350d-8f44-425c-80b0-a09105e553b7' User entered 'None (0)'	System	22 Oct 2020 12:50:07
	System	22 Oct 2020 12:50:07

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:45', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2fa9350d-8f44-425c-80b0-a09105e553b7' User entered 'None (0)'	System	22 Oct 2020 12:50:07
	System	22 Oct 2020 12:50:07

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:48', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2fa9350d-8f44-425c-80b0-a09105e553b7' User entered 'None (0)'	System	22 Oct 2020 12:50:07
	System	22 Oct 2020 12:50:07

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:51', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2fa9350d-8f44-425c-80b0-a09105e553b7' User entered 'None (0)'	System	22 Oct 2020 12:50:07
	System	22 Oct 2020 12:50:07

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:53', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2fa9350d-8f44-425c-80b0-a09105e553b7' User entered 'None (0)'	System	22 Oct 2020 12:50:07
	System	22 Oct 2020 12:50:07

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:56', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2fa9350d-8f44-425c-80b0-a09105e553b7' User entered 'None (0)'	System	22 Oct 2020 12:50:07
	System	22 Oct 2020 12:50:07

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

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 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:49:59', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2fa9350d-8f44-425c-80b0-a09105e553b7'	System	22 Oct 2020 12:50:07
User entered 'No (N)'	System	22 Oct 2020 12:50:07

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BF52B09-E57B-4CB8-BA73-5633FE1CF961)', Time: '2020-10-22T05:50:01', User OID: 'PatientReportedOutcome (US3562230)', ODM File OID: '2fa9350d-8f44-425c-80b0-a09105e553b7' User entered '22 Oct 2020 05:50'	System	22 Oct 2020 12:50:07
	System	22 Oct 2020 12:50:07

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 21:07:26

US3562230

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:44
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 21:07:26

US3562230

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:06:14

US3562230

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '22 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:06:14

US3562230

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:06:14

US3562230

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:06:14

US3562230

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:06:18

US3562230

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'l'	System	22 Oct 2020 17:06:18

US3562230

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	30 Oct 2020 23:57:17

US3562230

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered '30 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	30 Oct 2020 23:57:17

US3562230

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	30 Oct 2020 23:57:17

US3562230

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	30 Oct 2020 23:57:17

US3562230

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	30 Oct 2020 23:57:21

US3562230

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'l'	System	30 Oct 2020 23:57:21

US3562230

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:19:26

US3562230

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 04:54:27
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CONFIRMED AS IT IS' (Site from System).	Dhwani Shah (b) (4)	16 Nov 2020 22:19:33
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Nov 2020 22:19:26
User entered '9 Nov 2020'	Dhwani Shah (b) (4)	16 Nov 2020 22:19:26

US3562230

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:19:26

US3562230

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:19:26

US3562230

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	16 Nov 2020 22:19:38

US3562230

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'l'	System	16 Nov 2020 22:19:38

US3562230

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:42

US3562230

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:42

US3562230

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

[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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:42

US3562230

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'VISIT2'	System	26 Jan 2021 21:47:42

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:47:50

US3562230

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:55

US3562230

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:47:55

US3562230

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:02

US3562230

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	26 Jan 2021 21:48:39
User entered 'Withdrawal of Consent by Participant (WITHDRAWAL OF CONSENT)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	26 Jan 2021 21:48:39
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	26 Jan 2021 21:48:02
User entered empty.	Dhwani Shah (b) (4)	26 Jan 2021 21:48:02

US3562230

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'pt discontinue from study due to SAE'	(b) (4)	
reason for change: Data Entry Error	Dhwani Shah (b) (4)	26 Jan 2021 21:48:39
User entered empty.	(b) (4)	
	Dhwani Shah (b) (4)	26 Jan 2021 21:48:02
	(b) (4)	

US3562230

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:48:02

US3562230

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:02

US3562230

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:02

US3562230

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:48:02

US3562230

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:02

US3562230

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:48:02

US3562230

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:48:02

US3562230

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:44

US3562230

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:44

US3562230

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:44

US3562230

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:48:44

US3562230

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:16:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:51

US3562230

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:51

US3562230

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:51

US3562230

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:51

US3562230

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:48:51

US3562230

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:51

US3562230

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:51

US3562230

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:51

US3562230

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:48:51

US3562230

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:32
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Jan 2021 21:48:56

US3562230

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	26 Jan 2021 21:48:56

US3562230

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:16:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:40:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:03
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:13:02

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:05
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:08:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:08:33
Data point term sent to Coder	System	22 Oct 2020 17:07:52
User entered 'Diarrhea'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:07
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:09
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:11
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:25:26
User entered '22 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:25:28
User entered empty.	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:25:31
User closed query 'Please confirm response. Per progress note in source, diarrhea resolved on 23OCT2020. Please update as applicalbe. ' (Site from CRA).		23 Nov 2020 18:25:17
Query 'Please confirm response. Per progress note in source, diarrhea resolved on 23OCT2020. Please update as applicalbe. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 20:00:00
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 19:59:54
User opened query 'Please confirm response. Per progress note in source, diarrhea resolved on 23OCT2020. Please update as applicalbe. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:47:12
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:25:34
User entered '23 Oct 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	19 Nov 2020 19:59:54
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:25:37
User entered empty.	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:19
User entered 'Grade 1/Mild (Grade 1/Mild)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:21
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:27
User entered '0'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:29
User entered '0'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:34
User entered '0'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:36
User entered empty.	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:38
User entered empty.	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:40
User entered empty.	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:41
User entered empty.	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:43
User entered '0'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:44
User entered '0'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:46
User entered '0'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:48
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:49
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:48:55
User entered 'None (NONE)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:49:33
DataPoint Un-verified.		18 Nov 2020 18:49:02
DataPoint Verified.		18 Nov 2020 18:48:56
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:49:34
DataPoint Un-verified.		18 Nov 2020 18:49:30
DataPoint Verified.		18 Nov 2020 18:48:58
User entered '0'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:49:36
User entered '0'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:25:49
User closed query 'Please update as applicable. ' (Site from CRA).		23 Nov 2020 18:25:46
Query 'Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 20:00:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 19:59:54
User opened query 'Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:47:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:49:43
User entered empty.	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:49:45
User entered empty.	Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '0'	System	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '0'	System	22 Oct 2020 17:07:48

US3562230

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:49:58
Reviewed for Safety.		10 Nov 2020 16:52:22
User entered 'USA-US071-2020-mRNA-1273-P301000003'	System	10 Nov 2020 16:51:35
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 16:51:35

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:07:33
User closed query 'PV Query: Please consider updating SAE term for liver nodules to liver abscesses' (Site from Safety).		15 Dec 2020 21:11:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Hepatobiliary and spleen infections, PT: Liver abscess, LLT: Liver abscess - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 17:19:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 17:19:55
Data point term sent to Coder	System	15 Dec 2020 17:18:11
Query 'PV Query: Please consider updating SAE term for liver nodules to liver abscesses' answered with 'updated' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:17:22
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:17:16
Coding entries removed.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:17:16
User entered 'LIVER abcess' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:17:16
User opened query 'PV Query: Please consider updating SAE term for liver nodules to liver abscesses' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 22:07:21
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:50:00
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic and hepatobiliary disorders NEC, PT: Hepatic mass, LLT: Liver nodule - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:32:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:32:41
Data point term sent to Coder	System	10 Nov 2020 00:31:22
User entered 'liver nodule'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:02
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:04
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:06
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:08
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:12
User entered empty.	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:07:38
DataPoint Un-verified.	Dhwani Shah (b) (4)	03 Dec 2020 19:21:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	03 Dec 2020 19:21:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:50:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:07:40
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		04 Dec 2020 13:46:27
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.' answered with 'updated' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 19:21:20
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 19:21:14
User entered '17 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 19:21:14
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)	19 Nov 2020 19:10:47
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:50:21
User entered empty.	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:22
User entered empty.	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
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)	01 Dec 2020 00:35:38
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)	01 Dec 2020 00:35:10
User entered empty.	System	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:25
User entered 'Grade 4 (Grade 4)'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:29
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:33
User entered '0'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:35
User entered '0'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:50:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		11 Nov 2020 06:08:01
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'already entered admission date. pt is still in hospital and discharge date is not available. ICU admitted is unknown and will updated once site has more info ' (Site from System).	Dhwani Shah (b) (4)	10 Nov 2020 00:32:02
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	10 Nov 2020 00:31:09
User entered 'I'	Dhwani Shah (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:42
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:14:13
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		23 Nov 2020 22:27:15
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:49:11
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:48:54
User entered '17 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:48:54
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 19:11:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:50:44
User entered empty.	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:46
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	10 Nov 2020 21:46:44
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		10 Nov 2020 21:46:44
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 21:46:44
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	10 Nov 2020 00:32:12
User entered 'Unknown (UNK)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:32:12
User entered empty.	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:52
User entered empty.	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:54
User entered '0'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:56
User entered '0'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:57
User entered '0'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:50:59
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:51:01
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:21:54
User closed query 'Please consider if this should be a different response as subject ended up withdrawing consent and not receiving 2nd dose due to the SAE. ' (Site from CRA).		16 Dec 2020 22:21:51
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		16 Dec 2020 00:25:38
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	16 Dec 2020 00:25:38
Query 'Please consider if this should be a different response as subject ended up withdrawing consent and not receiving 2nd dose due to the SAE. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:25:09
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	16 Dec 2020 00:24:38
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:24:38
User opened query 'Please consider if this should be a different response as subject ended up withdrawing consent and not receiving 2nd dose due to the SAE. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 23:17:38
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 23:16:24

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 23:12:34
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 23:11:35
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:14:29
User entered 'None (NONE)'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:08:22
User entered '0' reason for change: Data Entry Error	Dhwani Shah (b) (4)	15 Dec 2020 17:17:37
User entered '1'	(b) (4) Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:08:25
User entered '1' reason for change: Data Entry Error	Dhwani Shah (b) (4)	15 Dec 2020 17:17:37
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:08:27
User entered '0'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:08:30
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).		04 Dec 2020 13:46:31
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 19:21:29
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 19:21:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 19:21:14
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:14:49
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:48:54
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:48:54
Data Entry Error		
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)	19 Nov 2020 19:10:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:51:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:51:17
User entered empty.	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:08:46
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).		15 Dec 2020 21:11:45
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:17:45
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 13:46:35
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. ultrasound, CT, MRI, biopsy). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 13:46:34
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. ultrasound, CT, MRI, biopsy). Please include units and reference ranges if applicable.' answered with 'email medical records on 12/3/2020 to safety team' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 19:27:24

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'email medical records on 12/3/2020' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	03 Dec 2020 19:27:01
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. ultrasound, CT, MRI, biopsy). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 19:11:35
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)	19 Nov 2020 19:11:09
User entered 'pt developed symptoms like abdominal pain and dark urine. Went to ER on 11/7/2020 and got admitted. we will provide more info once site receive medical records'	Dhwani Shah (b) (4) (b) (4)	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'I'	System	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered 'I'	System	10 Nov 2020 00:31:09

US3562230

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '0'	System	10 Nov 2020 00:32:12

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 04:40:21
User closed query 'Per DM CLR: Please review recorded symptoms and verify if this was caused by an underlying medical condition. If yes, please update to record the underlying medical condition/diagnosis as appropriate. Otherwise, record each symptom individually.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 04:35:50
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'PROTOCOL DEVIATION IS CAPTURED IN SOURCE DOCUEMTNS' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:46:04
Query 'Per DM CLR: Please review recorded symptoms and verify if this was caused by an underlying medical condition. If yes, please update to record the underlying medical condition/diagnosis as appropriate. Otherwise, record each symptom individually.' answered with 'CONFIRMED AS IT IS' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	09 Feb 2021 19:41:23
User opened query 'Per DM CLR: Please review recorded symptoms and verify if this was caused by an underlying medical condition. If yes, please update to record the underlying medical condition/diagnosis as appropriate. Otherwise, record each symptom individually.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 13:51:20

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 05:09:21
	(b) (4), (b) (6)	15 Dec 2020 23:09:00
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever chills - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 17:51:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 17:51:15
Data point term sent to Coder	System	15 Dec 2020 17:19:14
User entered 'chills/Fever'	Dhwani Shah (b) (4)	15 Dec 2020 17:19:01
	(b) (4)	

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:05
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:06
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:11
User entered '01 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:20:13
User entered '09 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:13
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:14
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:16
User entered '07 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:20:13
User entered '09 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:24
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 17:19:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 17:19:09
User entered 'No (N)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:09
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 17:19:01
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:26
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:28
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:29
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:31
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:33
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:34
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:36
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:37
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:39
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:41
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:46
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:48
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:09:49
User entered 'None (NONE)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:10:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Dec 2020 17:19:09
User entered '1' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:09
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Dec 2020 17:19:01
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:10:27
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:10:28
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:10:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:10:33
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:10:35
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '0'	System	15 Dec 2020 17:19:09

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '0'	System	15 Dec 2020 17:19:01

US3562230

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:16:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 17:21:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 17:21:14
Data point term sent to Coder	System	15 Dec 2020 17:20:14
User entered 'abdominal pain'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered '01 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered 'None (NONE)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:11:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '0'	System	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '0'	System	15 Dec 2020 17:19:52

US3562230

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:16:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:51:44
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:13:22

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 18:15:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 18:15:27
Data point term sent to Coder	System	18 Oct 2020 18:15:08
User entered 'DIPHENHYDRAMINE'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered 'INSOMNIA'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered '50'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered 'as needed (PRN)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered empty.	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered 'UN UNK 2015'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered '0'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered empty.	Dhwani Shah (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:52:18
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	18 Oct 2020 18:14:15

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 16:41:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 16:41:01
Data point term sent to Coder	System	15 Dec 2020 16:39:43
User entered 'Influenza vaccine'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'flu prophylaxis'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'l'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'Other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'injection'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'once (ONCE)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'Intramuscular (INTRAMUSCULAR)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:39:31

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Dec 2020 21:00:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Dec 2020 21:00:43
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 23:19:00
Data point term sent to Coder	System	15 Dec 2020 16:41:44
User entered 'Heparin'	Dhwani Shah (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'blood clots prophylaxis'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '5000'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'Other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'units'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'every 8 hours'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'Subcutaneous (SUBCUTANEOUS)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:22:23
User closed query 'Please confirm stop date. Per source ConMed log, 17NOV2020 is captured. ' (Site from CRA).		16 Dec 2020 22:22:20
Query 'Please confirm stop date. Per source ConMed log, 17NOV2020 is captured. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:23:03
User entered '17 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:22:57
User opened query 'Please confirm stop date. Per source ConMed log, 17NOV2020 is captured. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 23:19:53
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 23:19:28
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:41:32

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 20:56:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 20:56:08
Data point term sent to Coder	System	15 Dec 2020 16:42:46
User entered 'vancomycin'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'liver abcess'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
User closed query 'Per DM CLR: Please provide the actual dose for this medication (in mg) instead of amount in mL, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 15:52:31
Query 'Per DM CLR: Please provide the actual dose for this medication (in mg) instead of amount in mL, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'confirmed as it is ! actual dose and units are unknown. ' (Site from DM).	Dhwani Shah (b) (4)	08 Feb 2021 15:52:43
User opened query 'Per DM CLR: Please provide the actual dose for this medication (in mg) instead of amount in mL, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 08:23:17
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '250'	Dhwani Shah (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'mL (mL)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'evry 6 hours'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'Intravenous (INTRAVENOUS)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:22:38
User closed query 'Please confirm response. Per source ConMed log, 17NOV2020 is captured. ' (Site from CRA).		16 Dec 2020 22:22:36
Query 'Please confirm response. Per source ConMed log, 17NOV2020 is captured. ' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4)	16 Dec 2020 00:23:19
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4)	16 Dec 2020 00:23:13
User opened query 'Please confirm response. Per source ConMed log, 17NOV2020 is captured. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 23:20:44
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 23:20:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '07 Nov 2020'	Dhwani Shah (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:42:46

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 10:10:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 10:10:43
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 23:19:00
Data point term sent to Coder	System	15 Dec 2020 16:44:47
User entered 'ondansetron'	Dhwani Shah (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'Nausea Prophylaxis'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '4'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'every 6 hours'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'Intravenous (INTRAVENOUS)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:22:52
User closed query 'Please confirm response. Per source ConMed log, 17NOV2020 is captured. ' (Site from CRA).		16 Dec 2020 22:22:49
Query 'Please confirm response. Per source ConMed log, 17NOV2020 is captured. ' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:23:33
User entered '17 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	16 Dec 2020 00:23:29
User opened query 'Please confirm response. Per source ConMed log, 17NOV2020 is captured. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 23:21:23
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 23:21:04
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:44:08

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 21:26:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 21:26:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 23:19:00
Data point term sent to Coder User entered 'hydralazine'	System Dhwani Shah (b) (4)	15 Dec 2020 16:49:51 15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
User closed query 'Per DM CLR: Prophylaxis is YES however Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable otherwise provide clarification if given as prevention.' (Site from DM). Query 'Per DM CLR: Prophylaxis is YES however Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable otherwise provide clarification if given as prevention.' answered with 'confirmed as it is !' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 15:54:27
User opened query 'Per DM CLR: Prophylaxis is YES however Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable otherwise provide clarification if given as prevention.' (Site from DM).	Dhwani Shah (b) (4)	08 Feb 2021 15:51:14
Data hard unlocked.	(b) (4), (b) (6)	28 Jan 2021 08:22:01
Data hard locked.	(b) (4), (b) (6)	28 Jan 2021 08:21:40
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 08:21:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 23:19:00
	Dhwani Shah (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'blood pressure prophylaxis'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '10'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'every 6 hours'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'Intravenous (INTRAVENOUS)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered empty.	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '0'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:23:04
User closed query 'Please confirm response. Per source ConMed log, 17NOV2020 is captured. ' (Site from CRA).		16 Dec 2020 22:23:01
Query 'Please confirm response. Per source ConMed log, 17NOV2020 is captured. ' answered with 'UPDATED' (Site from CRA).	Dhwani Shah (b) (4)	16 Dec 2020 00:23:57
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4)	16 Dec 2020 00:23:53
User opened query 'Please confirm response. Per source ConMed log, 17NOV2020 is captured. ' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 23:22:09
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 23:21:51
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered '07 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:19:00
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered empty.	System	15 Dec 2020 16:49:49

US3562230

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:16:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:22:26
User closed query 'Please update with any Con Procedures that may have occurred in relation to SAE. ' (Site from CRA).		15 Dec 2020 23:22:23
Query 'Please update with any Con Procedures that may have occurred in relation to SAE. ' answered with 'no procedure ' (Site from CRA).	Dhwani Shah (b) (4) (b) (4)	07 Dec 2020 22:28:53
User opened query 'Please update with any Con Procedures that may have occurred in relation to SAE. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:52:57
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	18 Oct 2020 18:13:09

US3562230

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:16:59

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:16:47
User entered '20 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:56:56

US3562230

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:16:59

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:14:13
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
DataPoint Un-verified.	(b) (4)	
	Dhwani Shah (b) (4)	16 Dec 2020 00:25:38
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	16 Dec 2020 00:25:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:16:49
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Dhwani Shah (b) (4)	20 Nov 2020 21:56:56
	(b) (4)	

US3562230

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:14:15
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
User closed query 'Per CDM: Per sponsor review, please update specify field to include only AE, number sign, and number. (i.e. AE #2).' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 11:50:51
Query 'Per CDM: Per sponsor review, please update specify field to include only AE, number sign, and number. (i.e. AE #2).' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	04 Mar 2021 23:06:49
User entered 'AE # 2' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 23:06:43
User opened query 'Per CDM: Per sponsor review, please update specify field to include only AE, number sign, and number. (i.e. AE #2).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 20:07:41
User closed query 'Per CDM: Please update the AE logline number of the AE due to which study drug was discontinued. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 06:44:27
Query 'Per CDM: Please update the AE logline number of the AE due to which study drug was discontinued. ' answered with 'UPDATED' (Site from DM).	Dhwani Shah (b) (4)	26 Jan 2021 21:50:31
DataPoint Un-verified.	Dhwani Shah (b) (4)	26 Jan 2021 21:50:27
User entered 'PT DOES NOT WANT TO CONTINUE WITH STUDY AS HE RECENTLY GOT DISCHARGE FROM HOSPITAL AE # 2' reason for change: Data Entry Error	Dhwani Shah (b) (4)	26 Jan 2021 21:50:27
User opened query 'Per CDM: Please update the AE logline number of the AE due to which study drug was discontinued. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:04:07

US3562230

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:16:59

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

Audit	User	Time (GMT)
Query 'Per CDM: Please update the AE logline number due to which the study drug was discontinued in this field.' canceled (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:03:19
User opened query 'Per CDM: Please update the AE logline number due to which the study drug was discontinued in this field.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:03:01
Query 'Per CDM: Please update the AE logline number as the reason for dosing discontinuation is SAE.' canceled (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:01:57
User opened query 'Per CDM: Please update the AE logline number as the reason for dosing discontinuation is SAE.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:00:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:16:51
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	20 Nov 2020 21:57:43
User entered 'pt does not want to continue with study as he recently got discharge from hospital' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:57:43
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	20 Nov 2020 21:56:56
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:56:56

US3562230

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:16:59

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:17:08
User entered '20 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:58:24

US3562230

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:16:59

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:17:08
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:58:24

US3562230

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:17:08
User entered 'doe not want to continue with study due to recent hospitalized'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:58:24

US3562230

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:16:59

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:17:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:58:24

US3562230

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:16:59

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:17:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:58:24

US3562230

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:16:59

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:17:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:58:24

US3562230

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:16:59

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:39:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:17:08
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 21:58:24

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'USA-US071-2020-MRNA-1273-P301000003'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Joseph'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Davis'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered '3900 E Camel Back road'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Phoenix'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered '85018'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
Reviewed for Safety.	(b) (4)	04 Dec 2020 13:46:46
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:49
User entered 'US'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '5'	System	16 Dec 2020 13:55:59
User entered '4'	System	15 Dec 2020 20:53:15
User entered '3'	System	04 Dec 2020 13:46:54
User entered '2'	System	23 Nov 2020 22:49:00
User entered '1'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'USA-US071-2020-MRNA-1273-P301000003'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Joseph'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Davis'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered '3900 E Camel Back road'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Phoenix'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered '85018'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
Reviewed for Safety.	(b) (4)	04 Dec 2020 13:46:46
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:49
User entered 'US'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '5'	System	16 Dec 2020 13:55:59
User entered '4'	System	15 Dec 2020 20:53:15
User entered '3'	System	04 Dec 2020 13:46:54
User entered '2'	System	23 Nov 2020 22:49:00
User entered '1'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:16:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
User entered '10/Nov/2020 11:52'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
Reviewed for Safety.	(b) (4)	04 Dec 2020 13:46:46
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:49
User entered 'I'		10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'USA-US071-2020-MRNA-1273-P301000003'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Joseph'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Davis'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered '3900 E Camel Back road'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Phoenix'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:52:45
User entered '85018'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
Reviewed for Safety.	(b) (4)	04 Dec 2020 13:46:46
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:49
User entered 'US'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '5'	System	16 Dec 2020 13:55:59
User entered '4'	System	15 Dec 2020 20:53:15
User entered '3'	System	04 Dec 2020 13:46:54
User entered '2'	System	23 Nov 2020 22:49:00
User entered '1'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:16:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:05:32
User entered '23/Nov/2020 17:48'	System	23 Nov 2020 22:49:00

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:05:34
Reviewed for Safety.		04 Dec 2020 13:46:46
User entered 'I'		23 Nov 2020 22:49:00

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'USA-US071-2020-MRNA-1273-P301000003'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Joseph'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Davis'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered '3900 E Camel Back road'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Phoenix'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered '85018'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
Reviewed for Safety.	(b) (4)	04 Dec 2020 13:46:46
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:49
User entered 'US'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '5'	System	16 Dec 2020 13:55:59
User entered '4'	System	15 Dec 2020 20:53:15
User entered '3'	System	04 Dec 2020 13:46:54
User entered '2'	System	23 Nov 2020 22:49:00
User entered '1'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:16:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:05:52
User entered '04/Dec/2020 13:46'	System	04 Dec 2020 13:46:54

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:05:53
Reviewed for Safety.		15 Dec 2020 20:52:59
User entered 'I'		04 Dec 2020 13:46:54

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'USA-US071-2020-MRNA-1273-P301000003'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Joseph'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Davis'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered '3900 E Camel Back road'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Phoenix'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered '85018'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 13:46:46
DataPoint Verified.		18 Nov 2020 18:39:49
User entered 'US'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '5'	System	16 Dec 2020 13:55:59
User entered '4'	System	15 Dec 2020 20:53:15
User entered '3'	System	04 Dec 2020 13:46:54
User entered '2'	System	23 Nov 2020 22:49:00
User entered '1'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:16:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:07:01
User entered '15/Dec/2020 15:53'	System	15 Dec 2020 20:53:15

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 23:07:03
User entered 'l'		15 Dec 2020 20:53:15

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'USA-US071-2020-MRNA-1273-P301000003'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Yes (Y)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'No (N)'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Joseph'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered 'Davis'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered '3900 E Camel Back road'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:52:45
User entered 'Phoenix'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:49
Reviewed for Safety.		10 Nov 2020 16:52:45
User entered '85018'	System	10 Nov 2020 16:51:35

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
Reviewed for Safety.	(b) (4)	04 Dec 2020 13:46:46
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:49
User entered 'US'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User entered '5'	System	16 Dec 2020 13:55:59
User entered '4'	System	15 Dec 2020 20:53:15
User entered '3'	System	04 Dec 2020 13:46:54
User entered '2'	System	23 Nov 2020 22:49:00
User entered '1'	System	10 Nov 2020 16:52:52

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:16:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
User entered '16/Dec/2020 07:55'	(b) (4) System	16 Dec 2020 13:55:59

US3562230

Folder: SAE USA-US071-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:16:59

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 19:27:34
User signature succeeded.	Joseph Davis (b) (4)	24 Mar 2021 18:37:10
User entered 'I'	(b) (4), (b) (6)	16 Dec 2020 13:55:59