

US3342088 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:07:37

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US3342088

Form: Participant Creation

Data signed: (b) (4) 12 Mar 2021 23:16:10

Generated On: 09 Jun 2021 17:07:37

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Mar 2021 23:16:15

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Date of Informed Consent (<i>dd MMM yyyy</i>)	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Mar 2021 23:16:15

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Mar 2021 13:27:11

Generated On: 09 Jun 2021 17:07:37

Condition	SULFA DRUG ALLERGY (RASH)
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Mar 2021 13:27:11

Generated On: 09 Jun 2021 17:07:37

Condition	TARSAL TUNNEL SYNDROME RIGHT FOOT
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Mar 2021 13:27:11

Generated On: 09 Jun 2021 17:07:37

Condition	TARSAL TUNNEL SURGERY RIGHT FOOT
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Mar 2021 13:27:11

Generated On: 09 Jun 2021 17:07:37

Condition	MINOR ABRASION LEFT UE FROM BURN FROM GREASE FRYER
Start date (dd MMM yyyy)	12 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Mar 2021 13:27:11

Generated On: 09 Jun 2021 17:07:37

Condition	TRAUMATIC AMPUTATION OF L 3RD DISTAL END OF DIGIT
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	15:31 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 15:31
Height (xxx.x)	165.0 cm
Weight (xxx.x)	84.5 kg
BMI (xxx.x)	31.03765 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:16:15

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Mar 2021 23:16:15

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Date of assessment (dd MMM yyyy) 17 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	17 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:16:15

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:16:15

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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	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:16:15

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Mar 2021 13:27:11

Generated On: 09 Jun 2021 17:07:37

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 105305

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Mar 2021 23:16:15

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	15:31 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 15:31
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	17:27 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 17:27
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 12 Mar 2021 23:16:15

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Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 16:57 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 16:57

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 AUG 2020
Collection time (00:00-23:59)	16:33 (24 HR)
Collection date and time (derived)	17 AUG 2020 16:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:35	17 AUG 2020 16:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 17:29

PC Open Date & Time

17 AUG 2020 17:17

PC Close Date & Time

17 AUG 2020 19:47

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	17 AUG 2020 21:32
PC Open Date & Time	17 AUG 2020 20:42
PC Close Date & Time	18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 12:02

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

19 AUG 2020 12:37

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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 AUG 2020 12:38

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

21 AUG 2020 12:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

22 AUG 2020 12:01

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 12:11

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

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

17 AUG 2020 17:30

PC Open Date & Time

17 AUG 2020 17:17

PC Close Date & Time

17 AUG 2020 19:47

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

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

17 AUG 2020 21:33

PC Open Date & Time

17 AUG 2020 20:42

PC Close Date & Time

18 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:37

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

18 AUG 2020 12:02

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:37

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

19 AUG 2020 12:38

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:37

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

20 AUG 2020 12:39

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:37

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

21 AUG 2020 12:02

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:37

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

22 AUG 2020 12:01

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	23 AUG 2020 12:11
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

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 ☐

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 17:30
PC Open Date & Time	17 AUG 2020 17:17
PC Close Date & Time	17 AUG 2020 19:47

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

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 ☐

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 21:33
PC Open Date & Time	17 AUG 2020 20:42
PC Close Date & Time	18 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

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 ☒

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 12:03
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

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

51 of 1135

EAB) (1725)

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:38
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

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

53 of 1135

EAB) (1725)

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:39
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

55 of 1135

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:03
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

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

57 of 1135

EAB) (1725)

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:01
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

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

59 of 1135

EAB) (1725)

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:11
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3342088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342088

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3342088

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342088

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	13:41 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 13:41
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3342088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	17 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

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 SAE NEW DX OF COLON CANCER

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? _____

US3342088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

14:12 (24 HR)

Collection date and time (derived)

17 SEP 2020 14:12

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:13	17 SEP 2020 14:13
Nasopharyngeal Swab 2	No		

US3342088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments VM LEFT ON 24SEP2020,
25SEP2020, AND 28SEP2020

If Contact Not Made, please provide Comments

US3342088

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342088

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342088

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	13:13 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 13:13
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

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.

US3342088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

14:02 (24 HR)

Collection date and time (derived)

14 OCT 2020 14:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 OCT 2020 08:23:07
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 21:58:27

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 08:45:31
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 12:06:33
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 07:32:30

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 07:22:53
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 07:54:54
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 11:28:54

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 14:13:40

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 07:37:51

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 07:28:12

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3342088

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:07:37

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3342088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

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

US3342088

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:16:15

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342088

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342088

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Mar 2021 13:27:11

Generated On: 09 Jun 2021 17:07:37

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3342088

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:07:37

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3342088

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:07:37

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3342088

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 16:32:43

Generated On: 09 Jun 2021 17:07:37

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

US3342088

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:16:10

Generated On: 09 Jun 2021 17:07:37

AEID	USA-US203-2020-MRNA-1273-P30 1000001
Adverse event	STAGE III COLON CANCER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:16:10

Generated On: 09 Jun 2021 17:07:37

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:16:10

Generated On: 09 Jun 2021 17:07:37

PATIENT DIAGNOSED WITH COLON CANCER ON 15SEP2020. NO STAGE WAS DETERMINED AND SURGERY HAS YET TO BE SCHEDULED. PATIENT SAYS CHEMOTHERAPY IS NOT EXPECTED AND SHOULD ONLY REQUIRE SURGERY. PATIENT UNDERWENT COLONIC TUMOR RESECTION WITH ILEOSTOMY ON 30SEP2020 (NOTED IN SOURCE 16OCT2020 PROGRESS NOTE). CON MEDICATION GIVEN FOR POST OPERATIVE PAIN MANAGEMENT (700MG ACETAMINOPHEN QID/PRN PO [START 30SEP2020, END 03OCT2020]). UPDATED CON MED LIST. DAO 05NOV2020.

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)	

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

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

Yes ☒

No ☐

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

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 16:32:43

Generated On: 09 Jun 2021 17:07:37

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication WELLNESS

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)

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US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 16:32:43

Generated On: 09 Jun 2021 17:07:37

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 16:32:43

Generated On: 09 Jun 2021 17:07:37

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN
(COLONIC TUMOR RESECTION)

Dose per administration 700

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 16:32:43

Generated On: 09 Jun 2021 17:07:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 16:32:43

Generated On: 09 Jun 2021 17:07:37

Name of Medication MRNA-1273 VACCINE

Prophylaxis Yes ☒
No ☐

Indication COVID-19

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 16:32:43

Generated On: 09 Jun 2021 17:07:37

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2021
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN UNK 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 16:32:43

Generated On: 09 Jun 2021 17:07:37

Name of Medication MRNA-1273 VACCINE

Prophylaxis Yes ☒
No ☐

Indication COVID-19

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 16:32:43

Generated On: 09 Jun 2021 17:07:37

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
30 SEP 2020	COLONIC TUMOR RESECTION	Adverse Event	
30 SEP 2020	ILEOSTOMY	Adverse Event	
16 OCT 2020	MRI POWER-PORT (FOR CHEMOTHERAPY) RIGHT SUBCLAVIAN.	Adverse Event	
31 AUG 2020	COLONOSCOPY	Diagnostic	
31 AUG 2020	EGD	Diagnostic	
22 SEP 2020	CT SCAN (CHEST, ABD, PELV) WITH CONTRAST	Diagnostic	

US3342088

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

Date of dosing discontinuation (dd MMM yyyy) 17 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #1

US3342088

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 22 Mar 2021 13:27:11

Generated On: 09 Jun 2021 17:07:37

Date of study discontinuation/completion (dd MMM yyyy) 22 JAN 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input checked="" type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

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

SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF SITE (MODERNA PRODUCT MRNA-1273)

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

SAEID	USA-US203-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

SAEID	USA-US203-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	18/SEP/2020 12:04
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

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

SAEID	USA-US203-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/OCT/2020 11:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

SAEID	USA-US203-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/OCT/2020 09:02
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

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Mar 2021 23:16:11

Generated On: 09 Jun 2021 17:07:37

SAEID	USA-US203-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 11:41
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

US3342088 (Prod: Tekton Research- Austin)

US3342088

Form: Participant Creation

Generated On: 09 Jun 2021 17:07:37

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:48:36
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'US3342088'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 20:53:16

US3342088

Form: Participant Creation

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:05:50

US3342088

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 20:53:17

US3342088

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Clinic (Clinic)'	John Luna (b) (4)	17 Aug 2020 22:05:50

US3342088

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'SCRN'	System	17 Aug 2020 22:05:50

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered (b) (6) 1970'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 20:53:18

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '50'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'YEARS'	System	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '50'	System	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Female (F)'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'I'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:37

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:37

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'Aug 2020'	System	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '2020'	System	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:37

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Amendment 2 (2)'	John Luna (b) (4)	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:37

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:37

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:37

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:37

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 20:53:17

US3342088

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:37

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'I'	System	17 Aug 2020 22:06:23

US3342088

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:06:23

US3342088

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:07:37

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:09:13

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 12:30:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 12:30:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 07:17:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 07:17:14
Data point term sent to Coder	System	17 Aug 2020 22:10:24
User entered 'Sulfa Drug Allergy (Rash)'	John Luna (b) (4)	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'un UNK 1990'	John Luna (b) (4)	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'Jan 1990'	System	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '1990'	System	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered empty.	System	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered empty.	System	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Tarsal tunnel syndrome, LLT: Tarsal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 07:03:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 07:03:17
Data point term sent to Coder	System	17 Aug 2020 22:10:24
User entered 'Tarsal Tunnel Syndrome Right Foot'	John Luna (b) (4)	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'un UNK 2018'	John Luna (b) (4)	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'un UNK 2018'	John Luna (b) (4)	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'Jan 2018'	System	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:37

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '2018'	System	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'Jan 2018'	System	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '2018'	System	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Tarsal tunnel decompression, LLT: Tarsal tunnel decompression - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 07:03:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 07:03:17
Data point term sent to Coder	System	17 Aug 2020 22:11:25
User entered 'Tarsal Tunnel Surgery Right Foot'	John Luna (b) (4)	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'un UNK 2018'	John Luna (b) (4)	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'un UNK 2018'	John Luna (b) (4)	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:37

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'Jan 2018'	System	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:37

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '2018'	System	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'Jan 2018'	System	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '2018'	System	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Skin injuries NEC, PT: Skin abrasion, LLT: Abrasion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:30:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:30:53
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:11
Data point term sent to Coder	System	18 Mar 2021 19:14:30
Coding entries removed.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:14:01
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:14:01
User entered 'Minor Abrasion Left UE From Burn from Grease Fryer' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:14:01
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries by physical agents, HLT: Thermal burns, PT: Thermal burn, LLT: Burn of unspecified degree of unspecified site of upper limb - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 09:51:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 09:51:31
Data point term sent to Coder	System	17 Aug 2020 22:41:01
User entered 'Left Arm Minor Burn'	John Luna (b) (4)	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '12 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'Aug 2020'	System	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '2020'	System	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered empty.	System	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered empty.	System	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb traumatic amputation, LLT: Finger traumatic amputation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 07:03:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 07:03:33
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:11
Data point term sent to Coder	System	18 Mar 2021 19:18:41
User entered 'Traumatic Amputation of L 3rd Distal End of Digit'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:18:32

US3342088

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:27:11
User entered 'UN UNK 1980'	Ethan Shotton (b) (4)	18 Mar 2021 19:18:32

US3342088

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:27:11
User entered '0'	Ethan Shotton (b) (4)	18 Mar 2021 19:18:32

US3342088

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:27:11
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	18 Mar 2021 19:18:48
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	18 Mar 2021 19:18:32
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:18:32

US3342088

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:27:11
User entered 'Un UNK 1980' reason for change:	(b) (4)	
Data Entry Error	Ethan Shotton (b) (4)	18 Mar 2021 19:18:48
User entered empty.	(b) (4)	
	Ethan Shotton (b) (4)	18 Mar 2021 19:18:32
	(b) (4)	

US3342088

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:27:11
User entered '0'	Ethan Shotton (b) (4)	18 Mar 2021 19:18:32

US3342088

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:37

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'Jan 1980'	System	18 Mar 2021 19:18:32

US3342088

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '1980'	System	18 Mar 2021 19:18:32

US3342088

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'Jan 1980'	System	18 Mar 2021 19:18:48
User entered empty.	System	18 Mar 2021 19:18:32

US3342088

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '1980'	System	18 Mar 2021 19:18:48
User entered empty.	System	18 Mar 2021 19:18:32

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '15:31'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '17 Aug 2020 15:31'	System	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '165.0' cm	(b) (4)	17 Aug 2020 22:12:15
DataPoint set to visible.	John Luna (b) (4)	17 Aug 2020 22:06:23
	System	17 Aug 2020 22:06:23

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '84.5' kg	(b) (4)	17 Aug 2020 22:12:15
DataPoint set to visible.	John Luna (b) (4)	17 Aug 2020 22:06:23
	System	17 Aug 2020 22:06:23

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
Amendment Manager: User entered '31.03765'	System	17 Sep 2020 00:00:59
User entered '31.0'	System	17 Aug 2020 22:12:15
DataPoint set to visible.	System	17 Aug 2020 22:06:23

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'kg/m2'	System	17 Aug 2020 22:12:15
DataPoint set to visible.	System	17 Aug 2020 22:06:23

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:42:52
User entered '98.3' F	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	
	John Luna (b) (4)	25 Aug 2020 17:42:52
User entered 'Oral (Oral)'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:42:52
User entered '59'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'bpm'	System	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:42:52
User entered '12'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'breaths/min'	System	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:42:52
User entered '116'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'mmHg'	System	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:42:52
User entered '76'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'mmHg'	System	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41

US3342088

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:12:23

US3342088

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:12:23

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:37

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:37

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:37

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Urine (URINE)'	John Luna (b) (4)	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Negative (NEGATIVE)'	John Luna (b) (4)	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User closed query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 06:48:54
Query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' answered with 'data updated' (Site from DM).	John Luna (b) (4)	09 Sep 2020 23:40:34
User opened query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 09:16:51
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	
	John Luna (b) (4)	09 Sep 2020 23:40:44
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	
	John Luna (b) (4)	09 Sep 2020 23:40:44
User entered '16:12'	John Luna (b) (4)	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered empty.	System	09 Sep 2020 23:40:44
User entered '17 Aug 2020 16:12'	System	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	(b) (4) John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	(b) (4) John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	(b) (4) John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'I'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:15:25

US3342088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:15:25

US3342088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Clinic (Clinic)'	John Luna (b) (4)	17 Aug 2020 22:15:25

US3342088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'VISIT1'	System	17 Aug 2020 22:15:25

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:41:17

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:09:46
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:09:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 21:41:17
User entered '105305' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:41:17

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:41:17

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:07:00

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:07:00

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	(b) (4) John Luna (b) (4)	17 Aug 2020 22:07:00

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:37

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:07:00

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:37

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:07:00

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:27:11
User entered 'No (N)'	Ethan Shotton (b) (4)	18 Mar 2021 18:55:36
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:23:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:45:04

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:42:24
User entered '165.0' cm	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:42:24
User entered '84.5' kg	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:42:24
User entered '165.0' cm	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User entered '84.5' kg	John Luna (b) (4)	25 Aug 2020 17:42:24
	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User accepted default value 'Pre-Dose (PREDOSE)'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Aug 2020'	(b) (4) John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '15:31'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '17 Aug 2020 15:31'	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '98.3' F	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Oral (Oral)'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	(b) (4) John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '59'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'bpm'	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '12'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'breaths/min'	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '116'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'mmHg'	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '76'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'mmHg'	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:42:24
User entered '165.0' cm	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:42:24
User entered '84.5' kg	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User accepted default value 'Post-Dose (POSTDOSE)'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Aug 2020 22:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 22:39:09
User entered 'Yes (Y)' reason for change: Data Entry Error	John Luna (b) (4)	17 Aug 2020 22:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 22:17:17
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:47:42
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 22:39:09
User entered '17:27' reason for change: Data Entry Error	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '17 Aug 2020 17:27'	System	17 Aug 2020 22:39:09
User entered empty.	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '98.2' F reason for change: Data Entry Error	(b) (4)	
	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '56' reason for change: Data Entry Error	(b) (4)	
	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'bpm'	System	17 Aug 2020 22:39:09
User entered empty.	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '12' reason for change: Data Entry Error	(b) (4)	
	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'breaths/min'	System	17 Aug 2020 22:39:09
User entered empty.	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '122' reason for change: Data Entry Error	(b) (4)	
	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'mmHg'	System	17 Aug 2020 22:39:09
User entered empty.	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '81' reason for change: Data Entry Error	(b) (4)	
	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'mmHg'	System	17 Aug 2020 22:39:09
User entered empty.	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	John Luna (b) (4)	25 Aug 2020 17:42:11
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:15:31

US3342088

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	
	John Luna (b) (4)	25 Aug 2020 17:42:11
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:15:31

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User closed query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:24:02
Query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' answered with 'Pregnancy test listed in screening visit only.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:39:42
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:39:02
User opened query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:57:23
User closed query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:57:16

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

Was the pregnancy test performed?

Audit	User	Time (GMT)
Query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' answered with 'Per CRF guidelines, both screening and baseline pregnancy test CRFs are to be completed if dosed same day as screening' (Site from DM).	Eileen Euperio (b) (4)	25 Sep 2020 14:42:29
User opened query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:09:56
User closed query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 19:58:43
Query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' answered with 'Understood. However, per the current eCRF Completion Guidelines, pages 15 and 16, under "DATA REQUIREMENTS", the information required to be input is listed as "Pregnancy Test (if applicable)" in the Screening Visit folder and again information is required to be input listed as "Pregnancy Test (if applicable)" in the Visit 1 Day 1 folder.' (Site from DM).	Darrell O'Brien (b) (4)	11 Sep 2020 23:11:46

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EAB) (1725)

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

Was the pregnancy test performed?

Audit	User	Time (GMT)
User opened query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 07:46:51
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 07:46:51
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'Per eCRF guide, data entered on both pages.' (Site from DM).	John Luna (b) (4)	09 Sep 2020 23:40:21
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 09:17:01
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4) Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered '17 Aug 2020'	(b) (4) John Luna (b) (4)	17 Aug 2020 22:15:57

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	
	Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered 'Urine (URINE)'	(b) (4)	
	John Luna (b) (4)	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	
	Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered 'Negative (NEGATIVE)'	(b) (4)	
	John Luna (b) (4)	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4) Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered 'No (N)'	(b) (4) John Luna (b) (4)	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	
	Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered '17 Aug 2020'	(b) (4)	
	John Luna (b) (4)	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	
	Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered '16:12'	(b) (4)	
	John Luna (b) (4)	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered empty.	System	05 Nov 2020 22:39:02
User entered '17 Aug 2020 16:12'	System	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '16:57'	John Luna (b) (4)	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '17 Aug 2020 16:57'	System	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Right Arm (RIGHT ARM)'	John Luna (b) (4)	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'ONCE'	System	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	19 Aug 2020 22:31:55

US3342088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Aug 2020'	Eileen Euperio (b) (4)	19 Aug 2020 22:31:55

US3342088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '16:33'	Eileen Euperio (b) (4)	19 Aug 2020 22:31:55

US3342088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '17 Aug 2020 16:33'	System	19 Aug 2020 22:31:55

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:07:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Aug 2020'	Eileen Euperio (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Eileen Euperio (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '16:35'	(b) (4) Eileen Euperio (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:37

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '17 Aug 2020 16:35'	System	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Eileen Euperio (b) (4) (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	(b) (4) Eileen Euperio (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	(b) (4) Eileen Euperio (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:37

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered empty.	System	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:16:07

US3342088

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '1'	System	17 Aug 2020 22:16:07

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:09', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a781a35d-0da9-47ba-b160-58d7e3df15c1'	System	17 Aug 2020 22:29:28
User entered 'Yes (Y)'	System	17 Aug 2020 22:29:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:16', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a781a35d-0da9-47ba-b160-58d7e3df15c1'	System	17 Aug 2020 22:29:28
User entered '98.2'	System	17 Aug 2020 22:29:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a781a35d-0da9-47ba-b160-58d7e3df15c1'	System	17 Aug 2020 22:29:28
User entered 'No (N)'	System	17 Aug 2020 22:29:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:26', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a781a35d-0da9-47ba-b160-58d7e3df15c1'	System	17 Aug 2020 22:29:28
User entered '17 Aug 2020 17:29'	System	17 Aug 2020 22:29:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '17 Aug 2020 17:17'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '17 Aug 2020 19:47'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:29', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cc9c8d2f-2290-4407-9556-5a42efb398ad'	System	18 Aug 2020 02:32:47
User entered 'Yes (Y)'	System	18 Aug 2020 02:32:47

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:35', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cc9c8d2f-2290-4407-9556-5a42efb398ad'	System	18 Aug 2020 02:32:47
User entered '98.2'	System	18 Aug 2020 02:32:47

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:39', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cc9c8d2f-2290-4407-9556-5a42efb398ad'	System	18 Aug 2020 02:32:47
User entered 'No (N)'	System	18 Aug 2020 02:32:47

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:44', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cc9c8d2f-2290-4407-9556-5a42efb398ad'	System	18 Aug 2020 02:32:47
User entered '17 Aug 2020 21:32'	System	18 Aug 2020 02:32:47

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '17 Aug 2020 20:42'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 2'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:13', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8592fe6c-6cf6-4c50-8be6-b71eb18adddf'	System	18 Aug 2020 17:02:41
User entered 'Yes (Y)'	System	18 Aug 2020 17:02:41

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:18', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8592fe6c-6cf6-4c50-8be6-b71eb18addf'	System	18 Aug 2020 17:02:41
User entered '98.2'	System	18 Aug 2020 17:02:41

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8592fe6c-6cf6-4c50-8be6-b71eb18adddf'	System	18 Aug 2020 17:02:41
User entered 'No (N)'	System	18 Aug 2020 17:02:41

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:24', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8592fe6c-6cf6-4c50-8be6-b71eb18addf'	System	18 Aug 2020 17:02:41
User entered '18 Aug 2020 12:02'	System	18 Aug 2020 17:02:41

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 3'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:36', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '28a0cb03-c65c-46a3-ba23-ce923feb5c13'	System	19 Aug 2020 17:37:52
User entered 'Yes (Y)'	System	19 Aug 2020 17:37:52

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:41', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '28a0cb03-c65c-46a3-ba23-ce923feb5c13'	System	19 Aug 2020 17:37:52
User entered '97.2'	System	19 Aug 2020 17:37:52

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:45', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '28a0cb03-c65c-46a3-ba23-ce923feb5c13'	System	19 Aug 2020 17:37:52
User entered 'No (N)'	System	19 Aug 2020 17:37:52

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:50', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '28a0cb03-c65c-46a3-ba23-ce923feb5c13'	System	19 Aug 2020 17:37:52
User entered '19 Aug 2020 12:37'	System	19 Aug 2020 17:37:52

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 4'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:37', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '5f8d09f0-3f65-49ae-ab96-50b95651cb12'	System	20 Aug 2020 17:38:54
User entered 'Yes (Y)'	System	20 Aug 2020 17:38:54

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:44', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '5f8d09f0-3f65-49ae-ab96-50b95651cb12'	System	20 Aug 2020 17:38:54
User entered '98.2'	System	20 Aug 2020 17:38:54

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:47', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '5f8d09f0-3f65-49ae-ab96-50b95651cb12'	System	20 Aug 2020 17:38:54
User entered 'No (N)'	System	20 Aug 2020 17:38:54

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:51', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '5f8d09f0-3f65-49ae-ab96-50b95651cb12'	System	20 Aug 2020 17:38:54
User entered '20 Aug 2020 12:38'	System	20 Aug 2020 17:38:54

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 5'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:01:39', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cbf0b95a-9327-425d-9987-2e792617295e'	System	21 Aug 2020 17:02:05
User entered 'Yes (Y)'	System	21 Aug 2020 17:02:05

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:01:47', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cbf0b95a-9327-425d-9987-2e792617295e' User entered '97.4'	System	21 Aug 2020 17:02:05
	System	21 Aug 2020 17:02:05

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:01:50', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cbf0b95a-9327-425d-9987-2e792617295e'	System	21 Aug 2020 17:02:05
User entered 'No (N)'	System	21 Aug 2020 17:02:05

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:01:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cbf0b95a-9327-425d-9987-2e792617295e'	System	21 Aug 2020 17:02:05
User entered '21 Aug 2020 12:01'	System	21 Aug 2020 17:02:05

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 6'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:12', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '9cc8c185-0bca-4c73-ae1c-1c49795899b9'	System	22 Aug 2020 17:01:29
User entered 'Yes (Y)'	System	22 Aug 2020 17:01:29

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:18', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '9cc8c185-0bca-4c73-ae1c-1c49795899b9' User entered '98.4'	System	22 Aug 2020 17:01:29
	System	22 Aug 2020 17:01:29

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:23', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '9cc8c185-0bca-4c73-ae1c-1c49795899b9'	System	22 Aug 2020 17:01:29
User entered 'No (N)'	System	22 Aug 2020 17:01:29

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:26', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '9cc8c185-0bca-4c73-ae1c-1c49795899b9'	System	22 Aug 2020 17:01:29
User entered '22 Aug 2020 12:01'	System	22 Aug 2020 17:01:29

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 7'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:10:59', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '1a6551a1-e750-4515-9dc2-bb931ede3fe3'	System	23 Aug 2020 17:11:10
User entered 'Yes (Y)'	System	23 Aug 2020 17:11:10

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:03', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '1a6551a1-e750-4515-9dc2-bb931ede3fe3'	System	23 Aug 2020 17:11:10
User entered '98.2'	System	23 Aug 2020 17:11:10

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:05', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '1a6551a1-e750-4515-9dc2-bb931ede3fe3'	System	23 Aug 2020 17:11:10
User entered 'No (N)'	System	23 Aug 2020 17:11:10

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:08', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '1a6551a1-e750-4515-9dc2-bb931ede3fe3'	System	23 Aug 2020 17:11:10
User entered '23 Aug 2020 12:11'	System	23 Aug 2020 17:11:10

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:49', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b56cca59-ac60-4027-a1c6-a88588f87cbd'	System	17 Aug 2020 22:30:07
User entered 'None (1)'	System	17 Aug 2020 22:30:07

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:53', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b56cca59-ac60-4027-a1c6-a88588f87cbd'	System	17 Aug 2020 22:30:07
User entered 'No (N)'	System	17 Aug 2020 22:30:07

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:56', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b56cca59-ac60-4027-a1c6-a88588f87cbd'	System	17 Aug 2020 22:30:07
User entered 'No (N)'	System	17 Aug 2020 22:30:07

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:00', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b56cca59-ac60-4027-a1c6-a88588f87cbd'	System	17 Aug 2020 22:30:07
User entered 'None (1)'	System	17 Aug 2020 22:30:07

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:03', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b56cca59-ac60-4027-a1c6-a88588f87cbd'	System	17 Aug 2020 22:30:07
User entered '17 Aug 2020 17:30'	System	17 Aug 2020 22:30:07

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '17 Aug 2020 17:17'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '17 Aug 2020 19:47'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:48', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '31b29293-eeae-48de-8bb5-c1ea102f2a47'	System	18 Aug 2020 02:33:02
User entered 'None (1)'	System	18 Aug 2020 02:33:02

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:51', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '31b29293-eeae-48de-8bb5-c1ea102f2a47'	System	18 Aug 2020 02:33:02
User entered 'No (N)'	System	18 Aug 2020 02:33:02

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '31b29293-eeae-48de-8bb5-c1ea102f2a47'	System	18 Aug 2020 02:33:02
User entered 'No (N)'	System	18 Aug 2020 02:33:02

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:57', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '31b29293-eeae-48de-8bb5-c1ea102f2a47'	System	18 Aug 2020 02:33:02
User entered 'None (1)'	System	18 Aug 2020 02:33:02

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:00', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '31b29293-eeae-48de-8bb5-c1ea102f2a47'	System	18 Aug 2020 02:33:02
User entered '17 Aug 2020 21:33'	System	18 Aug 2020 02:33:02

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '17 Aug 2020 20:42'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 2'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:32', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '61ffe9e8-5ddc-4278-8324-1d9da43318c2'	System	18 Aug 2020 17:02:51
User entered 'None (1)'	System	18 Aug 2020 17:02:51

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:35', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '61ffe9e8-5ddc-4278-8324-1d9da43318c2'	System	18 Aug 2020 17:02:51
User entered 'No (N)'	System	18 Aug 2020 17:02:51

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:38', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '61ffe9e8-5ddc-4278-8324-1d9da43318c2'	System	18 Aug 2020 17:02:51
User entered 'No (N)'	System	18 Aug 2020 17:02:51

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:41', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '61ffe9e8-5ddc-4278-8324-1d9da43318c2'	System	18 Aug 2020 17:02:51
User entered 'None (1)'	System	18 Aug 2020 17:02:51

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:43', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '61ffe9e8-5ddc-4278-8324-1d9da43318c2'	System	18 Aug 2020 17:02:51
User entered '18 Aug 2020 12:02'	System	18 Aug 2020 17:02:51

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 3'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:53', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a94db318-d642-4bb1-afad-e0e15bc44583'	System	19 Aug 2020 17:38:05
User entered 'None (1)'	System	19 Aug 2020 17:38:05

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:56', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a94db318-d642-4bb1-afad-e0e15bc44583'	System	19 Aug 2020 17:38:05
User entered 'No (N)'	System	19 Aug 2020 17:38:05

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:58', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a94db318-d642-4bb1-afad-e0e15bc44583'	System	19 Aug 2020 17:38:05
User entered 'No (N)'	System	19 Aug 2020 17:38:05

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:00', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a94db318-d642-4bb1-afad-e0e15bc44583'	System	19 Aug 2020 17:38:05
User entered 'None (1)'	System	19 Aug 2020 17:38:05

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:03', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a94db318-d642-4bb1-afad-e0e15bc44583'	System	19 Aug 2020 17:38:05
User entered '19 Aug 2020 12:38'	System	19 Aug 2020 17:38:05

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 4'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a62bfe99-f3b0-40dd-9a1a-0dad3ec49ce2'	System	20 Aug 2020 17:39:08
User entered 'None (1)'	System	20 Aug 2020 17:39:08

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:57', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a62bfe99-f3b0-40dd-9a1a-0dad3ec49ce2'	System	20 Aug 2020 17:39:08
User entered 'No (N)'	System	20 Aug 2020 17:39:08

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:59', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a62bfe99-f3b0-40dd-9a1a-0dad3ec49ce2'	System	20 Aug 2020 17:39:08
User entered 'No (N)'	System	20 Aug 2020 17:39:08

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:01', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a62bfe99-f3b0-40dd-9a1a-0dad3ec49ce2'	System	20 Aug 2020 17:39:08
User entered 'None (1)'	System	20 Aug 2020 17:39:08

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:04', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a62bfe99-f3b0-40dd-9a1a-0dad3ec49ce2'	System	20 Aug 2020 17:39:08
User entered '20 Aug 2020 12:39'	System	20 Aug 2020 17:39:08

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 5'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:02', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '97f7867f-0ca5-4a73-957a-da59be967487'	System	21 Aug 2020 17:02:19
User entered 'None (1)'	System	21 Aug 2020 17:02:19

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:04', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '97f7867f-0ca5-4a73-957a-da59be967487'	System	21 Aug 2020 17:02:19
User entered 'No (N)'	System	21 Aug 2020 17:02:19

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:06', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '97f7867f-0ca5-4a73-957a-da59be967487'	System	21 Aug 2020 17:02:19
User entered 'No (N)'	System	21 Aug 2020 17:02:19

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:08', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '97f7867f-0ca5-4a73-957a-da59be967487'	System	21 Aug 2020 17:02:19
User entered 'None (1)'	System	21 Aug 2020 17:02:19

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:12', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '97f7867f-0ca5-4a73-957a-da59be967487'	System	21 Aug 2020 17:02:19
User entered '21 Aug 2020 12:02'	System	21 Aug 2020 17:02:19

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 6'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:30', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '13b6d9a6-3c25-431b-8b1f-05552802e960'	System	22 Aug 2020 17:01:39
User entered 'None (1)'	System	22 Aug 2020 17:01:39

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:32', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '13b6d9a6-3c25-431b-8b1f-05552802e960'	System	22 Aug 2020 17:01:39
User entered 'No (N)'	System	22 Aug 2020 17:01:39

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:33', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '13b6d9a6-3c25-431b-8b1f-05552802e960'	System	22 Aug 2020 17:01:39
User entered 'No (N)'	System	22 Aug 2020 17:01:39

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:35', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '13b6d9a6-3c25-431b-8b1f-05552802e960'	System	22 Aug 2020 17:01:39
User entered 'None (1)'	System	22 Aug 2020 17:01:39

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:37', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '13b6d9a6-3c25-431b-8b1f-05552802e960'	System	22 Aug 2020 17:01:39
User entered '22 Aug 2020 12:01'	System	22 Aug 2020 17:01:39

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 7'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:11', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '0d0533e8-f829-4fd3-a670-9a972de74d8a'	System	23 Aug 2020 17:11:21
User entered 'None (1)'	System	23 Aug 2020 17:11:21

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:13', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '0d0533e8-f829-4fd3-a670-9a972de74d8a'	System	23 Aug 2020 17:11:21
User entered 'No (N)'	System	23 Aug 2020 17:11:21

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:15', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '0d0533e8-f829-4fd3-a670-9a972de74d8a'	System	23 Aug 2020 17:11:21
User entered 'No (N)'	System	23 Aug 2020 17:11:21

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:16', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '0d0533e8-f829-4fd3-a670-9a972de74d8a'	System	23 Aug 2020 17:11:21
User entered 'None (1)'	System	23 Aug 2020 17:11:21

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:19', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '0d0533e8-f829-4fd3-a670-9a972de74d8a'	System	23 Aug 2020 17:11:21
User entered '23 Aug 2020 12:11'	System	23 Aug 2020 17:11:21

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:08', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:12', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:16', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:19', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:22', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:26', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'No (N)'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:29', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered '17 Aug 2020 17:30'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '17 Aug 2020 17:17'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '17 Aug 2020 19:47'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:04', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:06', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:08', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:09', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:11', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:12', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:16', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'No (N)'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:18', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered '17 Aug 2020 21:33'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '17 Aug 2020 20:42'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 2'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:47', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:49', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:50', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:52', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:56', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:59', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'No (N)'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:03:01', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered '18 Aug 2020 12:03'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 3'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:06', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:08', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:10', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:12', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:14', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:16', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'No (N)'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:24', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered '19 Aug 2020 12:38'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 4'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:07', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered 'None (0)'	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:09', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0' User entered 'None (0)'	System	20 Aug 2020 17:39:28
	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:11', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0' User entered 'None (0)'	System	20 Aug 2020 17:39:28
	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:13', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0' User entered 'None (0)'	System	20 Aug 2020 17:39:28
	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:15', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0' User entered 'None (0)'	System	20 Aug 2020 17:39:28
	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:17', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered 'None (0)'	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered 'No (N)'	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:24', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered '20 Aug 2020 12:39'	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 5'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:18', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:29', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:34', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:49', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:51', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:57', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'No (N)'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:03:00', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered '21 Aug 2020 12:03'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 6'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:40', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:41', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:43', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:44', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:46', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:47', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:49', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'No (N)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:52', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered '22 Aug 2020 12:01'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 7'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:23', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:24', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:26', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:27', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:29', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

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 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:32', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'No (N)'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:34', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered '23 Aug 2020 12:11'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	24 Aug 2020 20:39:29

US3342088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '24 Aug 2020'	Ethan Shotton (b) (4)	24 Aug 2020 20:39:29

US3342088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	24 Aug 2020 20:39:29

US3342088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	Ethan Shotton (b) (4)	24 Aug 2020 20:39:29

US3342088

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	24 Aug 2020 20:39:33

US3342088

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '1'	System	24 Aug 2020 20:39:33

US3342088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	31 Aug 2020 16:41:29

US3342088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '31 Aug 2020'	Ethan Shotton (b) (4)	31 Aug 2020 16:41:29

US3342088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	31 Aug 2020 16:41:29

US3342088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	31 Aug 2020 16:41:29

US3342088

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	31 Aug 2020 16:41:32

US3342088

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered 'I'	System	31 Aug 2020 16:41:32

US3342088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	08 Sep 2020 23:26:34

US3342088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '8 Sep 2020'	Ethan Shotton (b) (4)	08 Sep 2020 23:26:34

US3342088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	08 Sep 2020 23:26:34

US3342088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	08 Sep 2020 23:26:34

US3342088

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	08 Sep 2020 23:26:38

US3342088

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:51:41
User entered '1'	System	08 Sep 2020 23:26:38

US3342088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	17 Sep 2020 22:12:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4)	25 Nov 2020 03:25:00
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' answered with 'Immunogenicity Assessment form updated on EDC.' (Site from DM).	Ethan Shotton (b) (4)	05 Nov 2020 22:34:46
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:08:25
User entered '17 Sep 2020'	Morgan Schulle (b) (4)	17 Sep 2020 22:12:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4)	17 Sep 2020 22:12:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'VISIT2'	System	17 Sep 2020 22:12:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User accepted default value 'Pre-Dose (PREDOSE)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Sep 2020'	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '13:41'	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered '17 Sep 2020 13:41'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '98.7' F	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Oral (Oral)'	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '64'	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'bpm'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '14'	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'breaths/min'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '110'	(b) (4) Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'mmHg'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '76'	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'mmHg'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User accepted default value 'Post-Dose (POSTDOSE)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4)	02 Oct 2020 18:18:09
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	02 Oct 2020 18:17:55
User entered 'No (N)'	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55
	(b) (4)	

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered empty.	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	02 Oct 2020 18:18:09
User entered missing code ND - Not Done.	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55
	(b) (4)	

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	(b) (4) Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	(b) (4) Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	
	Eileen Euperio (b) (4)	02 Oct 2020 18:18:09
	(b) (4)	
User entered missing code ND - Not Done.	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55
	(b) (4)	

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered empty.	System	02 Oct 2020 18:18:09
User entered 'bpm'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	02 Oct 2020 18:18:09
User entered missing code ND - Not Done.	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55
	(b) (4)	

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered empty.	System	02 Oct 2020 18:18:09
User entered 'breaths/min'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	02 Oct 2020 18:18:09
User entered missing code ND - Not Done.	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55
	(b) (4)	

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered empty.	System	02 Oct 2020 18:18:09
User entered 'mmHg'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty; reason for change Data Entry Error	(b) (4)	02 Oct 2020 18:18:09
User entered missing code ND - Not Done.	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55
	(b) (4)	

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered empty.	System	02 Oct 2020 18:18:09
User entered 'mmHg'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	02 Oct 2020 18:18:24

US3342088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Sep 2020'	Eileen Euperio (b) (4)	02 Oct 2020 18:18:24

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Sep 2020'	Eileen Euperio (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Urine (URINE)'	Eileen Euperio (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Negative (NEGATIVE)'	Eileen Euperio (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	Eileen Euperio (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	Eileen Euperio (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	Eileen Euperio (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:37

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered empty.	System	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	Eileen Euperio (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Physician Decision (PHYSICIAN DECISION)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'SAE new dx of colon cancer'	Eileen Euperio (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered empty.	System	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	Eileen Euperio (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	Eileen Euperio (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered empty.	System	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	(b) (4) Eileen Euperio (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered empty.	System	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered empty.	System	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	17 Sep 2020 22:12:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Sep 2020'	Morgan Schulle (b) (4)	17 Sep 2020 22:12:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '14:12'	(b) (4) Morgan Schulle (b) (4)	17 Sep 2020 22:12:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered '17 Sep 2020 14:12'	System	17 Sep 2020 22:12:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:07:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '17 Sep 2020'	Morgan Schulle (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '14:13'	Morgan Schulle (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:37

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered '17 Sep 2020 14:13'	System	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	Morgan Schulle (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	Morgan Schulle (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:37

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered empty.	System	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	30 Sep 2020 22:14:36

US3342088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered '1'	System	30 Sep 2020 22:14:36

US3342088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	01 Oct 2020 21:24:33

US3342088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '24 Sep 2020'	Eileen Euperio (b) (4)	01 Oct 2020 21:24:33

US3342088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Contact Not Made (CONTACT NOT MADE)'	Eileen Euperio (b) (4)	01 Oct 2020 21:24:33

US3342088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'VM left on 24sep2020, 25sep2020, and 28sep2020'	(b) (4) Eileen Euperio (b) (4)	01 Oct 2020 21:24:33

US3342088

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	01 Oct 2020 21:24:38

US3342088

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'I'	System	01 Oct 2020 21:24:38

US3342088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	02 Oct 2020 18:19:41

US3342088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '2 Oct 2020'	Eileen Euperio (b) (4)	02 Oct 2020 18:19:41

US3342088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Contact Made (CONTACT MADE)'	Eileen Euperio (b) (4)	02 Oct 2020 18:19:41

US3342088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Eileen Euperio (b) (4)	02 Oct 2020 18:19:41

US3342088

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	02 Oct 2020 18:19:47

US3342088

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'I'	System	02 Oct 2020 18:19:47

US3342088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	05 Nov 2020 22:08:05

US3342088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '9 Oct 2020'	Ethan Shotton (b) (4)	05 Nov 2020 22:08:05

US3342088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	05 Nov 2020 22:08:05

US3342088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	05 Nov 2020 22:08:05

US3342088

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	05 Nov 2020 22:08:30

US3342088

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered '1'	System	05 Nov 2020 22:08:30

US3342088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	05 Nov 2020 22:09:53

US3342088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '14 Oct 2020'	Ethan Shotton (b) (4)	05 Nov 2020 22:09:53

US3342088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Clinic (Clinic)'	Ethan Shotton (b) (4)	05 Nov 2020 22:09:53

US3342088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'VISIT3'	System	05 Nov 2020 22:09:53

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '14 Oct 2020'	Ethan Shotton (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '13:13'	Ethan Shotton (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered '14 Oct 2020 13:13'	System	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '98.7' F	Ethan Shotton (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Oral (Oral)'	Ethan Shotton (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	Ethan Shotton (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '71'	Ethan Shotton (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'bpm'	System	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '12'	Ethan Shotton (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'breaths/min'	System	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '106'	Ethan Shotton (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'mmHg'	System	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '70'	Ethan Shotton (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'mmHg'	System	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32

US3342088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'No (N)'	Ethan Shotton (b) (4)	05 Nov 2020 22:11:08

US3342088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	Ethan Shotton (b) (4)	05 Nov 2020 22:11:08

US3342088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	05 Nov 2020 22:15:23

US3342088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '14 Oct 2020'	Ethan Shotton (b) (4)	05 Nov 2020 22:15:23

US3342088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '14:02'	Ethan Shotton (b) (4)	05 Nov 2020 22:15:23

US3342088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered '14 Oct 2020 14:02'	System	05 Nov 2020 22:15:23

US3342088

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	05 Nov 2020 22:15:27

US3342088

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered 'I'	System	05 Nov 2020 22:15:27

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 64'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-18T08:23:00', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '799a230f-eb78-4d20-8789-89b05503097f'	System	18 Oct 2020 13:23:12
User entered 'No (N)'	System	18 Oct 2020 13:23:12

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-18T08:23:03', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '799a230f-eb78-4d20-8789-89b05503097f'	System	18 Oct 2020 13:23:12
User entered 'No (N)'	System	18 Oct 2020 13:23:12

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-18T08:23:07', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '799a230f-eb78-4d20-8789-89b05503097f' User entered '18 Oct 2020 08:23:07'	System	18 Oct 2020 13:23:12
	System	18 Oct 2020 13:23:12

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 71'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-28T21:58:17', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '705df78f-9259-4763-8e20-d39d6f047000'	System	29 Oct 2020 02:58:35
User entered 'No (N)'	System	29 Oct 2020 02:58:35

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-28T21:58:22', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '705df78f-9259-4763-8e20-d39d6f047000'	System	29 Oct 2020 02:58:35
User entered 'No (N)'	System	29 Oct 2020 02:58:35

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-28T21:58:27', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '705df78f-9259-4763-8e20-d39d6f047000'	System	29 Oct 2020 02:58:35
User entered '28 Oct 2020 21:58:27'	System	29 Oct 2020 02:58:35

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 78'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-31T08:45:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'e5ab363e-ef5d-4591-9ca3-fef3cbdeb2a8'	System	31 Oct 2020 13:45:38
User entered 'No (N)'	System	31 Oct 2020 13:45:38

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-31T08:45:28', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'e5ab363e-ef5d-4591-9ca3-fef3cbdeb2a8'	System	31 Oct 2020 13:45:38
User entered 'No (N)'	System	31 Oct 2020 13:45:38

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-31T08:45:31', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'e5ab363e-ef5d-4591-9ca3-fef3cbdeb2a8' User entered '31 Oct 2020 08:45:31'	System	31 Oct 2020 13:45:38
	System	31 Oct 2020 13:45:38

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 92'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-11-16T12:06:03', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '6b3be40c-c559-49c4-9c83-c8843baf9acd'	System	16 Nov 2020 18:06:36
User entered 'No (N)'	System	16 Nov 2020 18:06:36

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-11-16T12:06:25', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '6b3be40c-c559-49c4-9c83-c8843baf9acd'	System	16 Nov 2020 18:06:36
User entered 'No (N)'	System	16 Nov 2020 18:06:36

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-11-16T12:06:33', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '6b3be40c-c559-49c4-9c83-c8843baf9acd' User entered '16 Nov 2020 12:06:33'	System	16 Nov 2020 18:06:36
	System	16 Nov 2020 18:06:36

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.		
	System	17 Aug 2020 22:07:28
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:36
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-11-25T07:31:27', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bae5add5-4f39-4aad-9e80-bcf7c0798b2a'	System	25 Nov 2020 13:32:32
User entered 'No (N)'	System	25 Nov 2020 13:32:32

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-11-25T07:32:27', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bae5add5-4f39-4aad-9e80-bcf7c0798b2a'	System	25 Nov 2020 13:32:32
User entered 'No (N)'	System	25 Nov 2020 13:32:32

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-11-25T07:32:30', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bae5add5-4f39-4aad-9e80-bcf7c0798b2a' User entered '25 Nov 2020 07:32:30'	System	25 Nov 2020 13:32:32
	System	25 Nov 2020 13:32:32

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-12-16T07:22:36', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '4f4412d3-b8a3-44be-b463-23b42e1e5643'	System	16 Dec 2020 13:23:05
User entered 'No (N)'	System	16 Dec 2020 13:23:05

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-12-16T07:22:47', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '4f4412d3-b8a3-44be-b463-23b42e1e5643'	System	16 Dec 2020 13:23:05
User entered 'Yes (Y)'	System	16 Dec 2020 13:23:05

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-12-16T07:22:49', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '4f4412d3-b8a3-44be-b463-23b42e1e5643'	System	16 Dec 2020 13:23:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 13:23:05

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-12-16T07:22:53', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '4f4412d3-b8a3-44be-b463-23b42e1e5643' User entered '16 Dec 2020 07:22:53'	System	16 Dec 2020 13:23:05
	System	16 Dec 2020 13:23:05

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-12-23T07:54:38', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '54f1baa7-043a-4c8f-9dfe-7131248699d8'	System	23 Dec 2020 13:55:04
User entered 'No (N)'	System	23 Dec 2020 13:55:04

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-12-23T07:54:45', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '54f1baa7-043a-4c8f-9dfe-7131248699d8'	System	23 Dec 2020 13:55:04
User entered 'Yes (Y)'	System	23 Dec 2020 13:55:04

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-12-23T07:54:48', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '54f1baa7-043a-4c8f-9dfe-7131248699d8'	System	23 Dec 2020 13:55:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 13:55:04

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-12-23T07:54:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '54f1baa7-043a-4c8f-9dfe-7131248699d8'	System	23 Dec 2020 13:55:04
User entered '23 Dec 2020 07:54:54'	System	23 Dec 2020 13:55:04

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-12-30T11:28:47', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '174d9d8d-e6c7-4a68-bf99-1f66b2531196'	System	30 Dec 2020 17:28:57
User entered 'No (N)'	System	30 Dec 2020 17:28:57

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-12-30T11:28:50', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '174d9d8d-e6c7-4a68-bf99-1f66b2531196'	System	30 Dec 2020 17:28:57
User entered 'No (N)'	System	30 Dec 2020 17:28:57

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-12-30T11:28:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '174d9d8d-e6c7-4a68-bf99-1f66b2531196'	System	30 Dec 2020 17:28:57
User entered '30 Dec 2020 11:28:54'	System	30 Dec 2020 17:28:57

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2021-01-07T14:13:34', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a7895f09-69d7-4940-86ab-f9a071289155'	System	07 Jan 2021 20:13:42
User entered 'No (N)'	System	07 Jan 2021 20:13:42

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2021-01-07T14:13:37', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a7895f09-69d7-4940-86ab-f9a071289155'	System	07 Jan 2021 20:13:42
User entered 'No (N)'	System	07 Jan 2021 20:13:42

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2021-01-07T14:13:40', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a7895f09-69d7-4940-86ab-f9a071289155'	System	07 Jan 2021 20:13:42
User entered '07 Jan 2021 14:13:40'	System	07 Jan 2021 20:13:42

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2021-01-14T07:37:45', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'ec3e59f0-6792-46ac-99f7-b87c5c70ea9a'	System	14 Jan 2021 13:37:52
User entered 'No (N)'	System	14 Jan 2021 13:37:52

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2021-01-14T07:37:47', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'ec3e59f0-6792-46ac-99f7-b87c5c70ea9a'	System	14 Jan 2021 13:37:52
User entered 'No (N)'	System	14 Jan 2021 13:37:52

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2021-01-14T07:37:51', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'ec3e59f0-6792-46ac-99f7-b87c5c70ea9a'	System	14 Jan 2021 13:37:52
User entered '14 Jan 2021 07:37:51'	System	14 Jan 2021 13:37:52

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2021-01-20T07:28:06', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '2d984d0e-da01-4fe8-8481-d3ff822f2174'	System	20 Jan 2021 13:28:17
User entered 'No (N)'	System	20 Jan 2021 13:28:17

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2021-01-20T07:28:10', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '2d984d0e-da01-4fe8-8481-d3ff822f2174'	System	20 Jan 2021 13:28:17
User entered 'No (N)'	System	20 Jan 2021 13:28:17

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2021-01-20T07:28:12', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '2d984d0e-da01-4fe8-8481-d3ff822f2174'	System	20 Jan 2021 13:28:17
User entered '20 Jan 2021 07:28:12'	System	20 Jan 2021 13:28:17

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:46:18

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:46:18

US3342088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:35:21

US3342088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:35:21

US3342088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:35:21

US3342088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:35:21

US3342088

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:35:27

US3342088

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:52:32
User entered '1'	System	09 Nov 2020 17:35:27

US3342088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	14 Dec 2020 21:32:58

US3342088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '14 Dec 2020'	Olivia Hapanowicz (b) (4)	14 Dec 2020 21:32:58

US3342088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Contact Made (CONTACT MADE)'	Olivia Hapanowicz (b) (4)	14 Dec 2020 21:32:58

US3342088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Olivia Hapanowicz (b) (4)	14 Dec 2020 21:32:58

US3342088

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	14 Dec 2020 21:33:05

US3342088

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered 'I'	System	14 Dec 2020 21:33:05

US3342088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	14 Jan 2021 21:55:18

US3342088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '14 Jan 2021'	Ethan Shotton (b) (4)	14 Jan 2021 21:55:18

US3342088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	14 Jan 2021 21:55:18

US3342088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	14 Jan 2021 21:55:18

US3342088

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:27:11
Signature has been broken.	Ethan Shotton (b) (4)	18 Mar 2021 18:54:08
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	18 Mar 2021 18:54:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	14 Jan 2021 21:55:37

US3342088

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	18 Mar 2021 18:54:08
User entered 'I'	System	14 Jan 2021 21:55:37

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User closed query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 12:52:16
Query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' answered with 'Data not needed as subject was withdrawn from the study for receiving an EUA vaccine outside of the site. Page to be inactivated.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:44:29
User opened query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 08:03:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:18
User closed query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:40:22
Query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' answered with 'please clarify at what the best course of action is here as neither apply to this subject which is why both are blank. pt did not come in for OL-D1 visit and was therefore not reconsented. pt was also unblinded after amendment 5.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	08 Apr 2021 12:40:10

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM). User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	08 Apr 2021 09:03:28 31 Mar 2021 19:15:44

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:18
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:15:44

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:29:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	23 Apr 2021 12:52:19
Query 'Data is required. Please complete.' answered with 'Data not needed as subject was withdrawn from the study for receiving an EUA vaccine outside of the site. Page to be inactivated.' (Site from System).	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 15:43:23
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:15:44

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:29:23
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Apr 2021 15:29:18
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	31 Mar 2021 19:15:44

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:29:23
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Apr 2021 15:29:18
User entered '22 Jan 2021'	(b) (4), (b) (6)	31 Mar 2021 19:15:44

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:29:23
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:18
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:15:44

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:29:23
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:18
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:15:44

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:29:23
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:18
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:15:44

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:29:23
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4) (b) (4)	22 Apr 2021 15:43:23
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Apr 2021 15:29:18
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 19:15:44

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	22 Apr 2021 15:43:23
User entered 'I'	System	31 Mar 2021 19:15:44

US3342088

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:37

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	31 Mar 2021 19:15:44

US3342088

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:08:12
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:02:19

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:00
User entered 'USA-US203-2020-mRNA-1273-P301000001'	System	18 Sep 2020 16:03:52
User entered 'New'	(b) (4), (b) (6)	18 Sep 2020 16:03:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Colorectal neoplasms malignant, PT: Colon cancer stage III, LLT: Colon cancer stage III - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 20:05:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 20:05:32
Data point term sent to Coder	System	14 Oct 2020 20:04:23
Coding entries removed.	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 20:04:22
User entered 'Stage III COLON CANCER' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 20:04:22
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Colorectal neoplasms malignant, PT: Colon cancer, LLT: Colon cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:06:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:06:43
Data point term sent to Coder	System	17 Sep 2020 22:06:17
User entered 'Colon Cancer'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '15 Sep 2020'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	
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 'Will do.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:00
DataPoint Verified.	Ethan Shotton (b) (4)	05 Nov 2020 22:20:53
	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:19:43
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)	15 Oct 2020 13:56:14
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:45:08
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'subject has since withdrawn from study; at time of withdrawal, subject still expected to undergo additional therapy; no baseline established at time of withdrawal, AE to remain open as not recovered/not resolved' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 16:08:07
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 11:56:47
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'SAE is not expected to resolve during the duration subject has participated in the study.' (Site from Safety).	Ethan Shotton (b) (4) (b) (4)	22 Jan 2021 17:48:52
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:58:02
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:09:54
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 'ongoing' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 22:03:11
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)	25 Sep 2020 15:16:30
User entered empty.	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'I'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:23:44
User opened query 'Action taken with investigational System product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).		17 Sep 2020 22:06:02
User entered 'Not Related (NOT RELATED)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'Not Related (NOT RELATED)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:30:26
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please update applicable details as appropriate. Otherwise, clarify. ' answered with 'Per CRF guidelines, subject is does not meet necessary criteria to withdraw from the study. Subject has discontinued dosing, but is still participating in the study and attending all visits.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:32:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:42:47
User closed query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:10:04
Query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' answered with 'updated dosing discontinuation form' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	25 Sep 2020 13:41:16

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:56:19
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:30:07
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:30:38
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 16:20:04
DataPoint Un-verified.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 16:19:41
User entered '0' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	05 Nov 2020 16:19:41
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 01:30:08
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '1'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:30:07
User closed query 'Per CDM: Concomitant Procedure is not checked, however a procedure has been added for "Colon Cancer". Please review and clarify or update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:30:40
Query 'Per CDM: Concomitant Procedure is not checked, however a procedure has been added for "Colon Cancer". Please review and clarify or update accordingly.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 16:20:09
DataPoint Un-verified.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 16:19:41
User entered '1' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	05 Nov 2020 16:19:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User opened query 'Per CDM: Concomitant Procedure is not checked, however a procedure has been added for "Colon Cancer". Please review and clarify or update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:14:20
User entered '0'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:45:17
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'subject has since withdrawn from study; at time of withdrawal, subject still expected to undergo additional therapy; no baseline established at time of withdrawal, AE to remain open as not recovered/not resolved' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 16:08:40
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 11:56:33
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:08:04
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 'Colon Cancer is not expected to completely resolve during subject's participation in this study' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	09 Nov 2020 17:12:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
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)	15 Oct 2020 13:56:33
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:10:01
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).	Eileen Euperio (b) (4)	09 Oct 2020 22:03:40
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	09 Oct 2020 22:03:33
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)	25 Sep 2020 15:16:58
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 22:09:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 22:09:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	17 Sep 2020 22:09:38
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 22:06:02
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
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)	20 Nov 2020 15:21:45
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 'REDATCTED RECORDS SENT VIA FAX 19NOV2020' (Site from Safety).	Eileen Euperio (b) (4)	19 Nov 2020 21:17:45
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)	13 Nov 2020 19:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:30:07
User closed query 'PV query: Please clarify if the colon cancer was identified during routine screening or if there were symptoms that prompted the evaluation for and diagnosis of colon cancer.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:23
User closed query 'PV Query: Please confirm the date of the tumor resection. Was the date 30 Sep 2020?' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:21
User closed query 'PV Query: Please provide pathology report, if available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:19
User closed query 'PV Query: Did the subject have any risk factors for colon cancer (i.e. cigarette smoking, family history, polyps, alcohol, etc)?' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide initial signs/symptoms experienced by subject with date of onset.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:15
User closed query 'PV Query: Please provide treatment given for the event including surgical treatments (including date and name of curative surgery). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).		06 Nov 2020 16:41:14
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		06 Nov 2020 16:41:12
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		06 Nov 2020 16:41:10
Query 'PV Query: Please provide initial signs/symptoms experienced by subject with date of onset.' answered with 'No initial s/s.' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 18:31:06
Query 'PV query: Please clarify if the colon cancer was identified during routine screening, or if there were symptoms that prompted the evaluation for and diagnosis of colon cancer.' answered with 'Routine screening.' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 18:30:54
Query 'PV Query: Please provide pathology report, if available.' answered with 'Pathology report: invasive colonic adenocarcinoma 30SEP2020.' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 18:28:03
Query 'PV Query: Did the subject have any risk factors for colon cancer (i.e. cigarette smoking, family history, polyps, alcohol, etc)?' answered with 'Family history of breast cancer.' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 18:25:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Sigmoid cancer from pathology report of biopsy of polyp removed from sigmoidal colon on 30SEP2020.' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 18:23:59
Query 'PV Query: Please confirm the date of the tumor resection. Was the date 30 Sep 2020?' answered with 'Confirmed' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 16:29:27
User entered 'PATIENT DIAGNOSED WITH COLON CANCER ON 15SEP2020. NO STAGE WAS DETERMINED AND SURGERY HAS YET TO BE SCHEDULED. PATIENT SAYS CHEMOTHERAPY IS NOT EXPECTED AND SHOULD ONLY REQUIRE SURGERY. PATIENT UNDERWENT COLONIC TUMOR RESECTION WITH ILEOSTOMY ON 30SEP2020 (NOTED IN SOURCE 16OCT2020 PROGRESS NOTE). CON MEDICATION GIVEN FOR POST OPERATIVE PAIN MANAGEMENT (700MG ACETAMINOPHEN QID/PRN PO [START 30SEP2020, END 03OCT2020]). UPDATED CON MED LIST. DAO 05NOV2020.' reason for change: New Information	Darrell O'Brien (b) (4)	05 Nov 2020 16:29:13
Query 'PV Query: Please provide treatment given for the event including surgical treatments (including date and name of curative surgery). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Updated' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 16:27:59
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Updated' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 16:27:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT DIAGNOSED WITH COLON CANCER ON 15SEP2020. NO STAGE WAS DETERMINED AND SURGERY HAS YET TO BE SCHEDULED. PATIENT SAYS CHEMOTHERAPY IS NOT EXPECTED AND SHOULD ONLY REQUIRE SURGERY. PATIENT UNDERWENT COLONIC TUMOR RESECTION WITH ILEOSTOMY ON 30SEP2020 (NOTED IN SOURCE 16OCT2020 Progress note). Con medication given for post operative pain management (700mg Acetaminophen PRN PO [Start 30SEP2020, End 03OCT2020]). Updated con med list. DAO 05NOV2020.' reason for change: New Information DataPoint Un-verified.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 16:27:40
	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 16:24:48
User entered 'PATIENT DIAGNOSED WITH COLON CANCER ON 15SEP2020. NO STAGE WAS DETERMINED AND SURGERY HAS YET TO BE SCHEDULED. PATIENT SAYS CHEMOTHERAPY IS NOT EXPECTED AND SHOULD ONLY REQUIRE SURGERY. Patient underwent Colonic Tumor Resection with Ileostomy on 30SEP2020 (noted in source 16OCT2020' reason for change: New Information DataPoint Verified.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 16:24:48
	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User opened query 'PV query: Please clarify if the colon cancer was identified during routine screening, or if there were symptoms that prompted the evaluation for and diagnosis of colon cancer.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 13:59:36
User opened query 'PV Query: Please confirm the date of the tumor resection. Was the date 30 Sep 2020?' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 13:59:15
User opened query 'PV Query: Please provide pathology report, if available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 15:17:51
User opened query 'PV Query: Did the subject have any risk factors for colon cancer (i.e. cigarette smoking, family history, polyps, alcohol, etc)?' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 15:17:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide initial signs/symptoms experienced by subject with date of onset.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 15:17:26
User opened query 'PV Query: Please provide treatment given for the event including surgical treatments (including date and name of curative surgery). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 15:17:14
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 15:16:43
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 15:16:06
User entered 'Patient diagnosed with colon cancer on 15Sep2020. No stage was determined and surgery has yet to be scheduled. Patient says chemotherapy is not expected and should only require surgery'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered '1'	System	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered '1'	System	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:07:37

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:16
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:15:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Jan 2021 14:30:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Jan 2021 14:30:40
Data point term sent to Coder	System	07 Jan 2021 14:29:18
Coding entries removed.	Eileen Euperio (b) (4)	07 Jan 2021 14:29:10
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)	22 Dec 2020 21:39:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 21:39:50
Data point term sent to Coder	System	22 Dec 2020 21:39:14
Coding entries removed.	(b) (4), (b) (6)	22 Dec 2020 21:38:54
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:04:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:04:53
Data point term sent to Coder	System	02 Oct 2020 18:16:42
User entered 'influenza vaccine'	Eileen Euperio (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User closed query 'Per CDM Re-query: Response noted. However, "Influenza Vaccine" is administered to prevent Influenza. Please kindly consider updating prophylaxis to yes. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 12:49:29
Query 'Per CDM Re-query: Response noted. However, "Influenza Vaccine" is administered to prevent Influenza. Please kindly consider updating prophylaxis to yes. Thank you' answered with 'Updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	15 Jan 2021 18:01:19
DataPoint Un-verified.	Olivia Hapanowicz (b) (4) (b) (4)	15 Jan 2021 18:01:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	15 Jan 2021 18:01:06
User opened query 'Per CDM Re-query: Response noted. However, "Influenza Vaccine" is administered to prevent Influenza. Please kindly consider updating prophylaxis to yes. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 13:48:58
User closed query 'Per CDM: Please confirm Prophylaxis=No, as indication is "Influenza Prophylaxis. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 13:48:58
Query 'Per CDM: Please confirm Prophylaxis=No, as indication is "Influenza Prophylaxis. Thank you' answered with 'updated to reflect source' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	07 Jan 2021 14:29:19
User opened query 'Per CDM: Please confirm Prophylaxis=No, as indication is "Influenza Prophylaxis. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 13:18:35
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'wellness' reason for change: Data Entry Error	(b) (4)	07 Jan 2021 14:29:10
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	Eileen Euperio (b) (4)	07 Jan 2021 14:29:10
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 13:16:49
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 21:39:02
User entered 'Influenza Prophylaxis' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 21:38:54
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 17:51:51
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'wellness'	Eileen Euperio (b) (4)	02 Oct 2020 18:16:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'l'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'Other (OTHER)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'injection'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'once (ONCE)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'Intramuscular (INTRAMUSCULAR)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '24 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '0'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '24 Sep 2020'	Eileen Euperio (b) (4)	02 Oct 2020 18:16:33

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	02 Oct 2020 18:16:33

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	02 Oct 2020 18:16:33

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	02 Oct 2020 18:16:33

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:05:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:05:30
Data point term sent to Coder	System	14 Oct 2020 19:05:10
User entered 'Acetaminophen'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'Post operative pain (Colonic Tumor Resection)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '700'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'mg (mg)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'as needed (PRN)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'Oral (ORAL)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '30 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '03 Oct 2020'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 13:13:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 13:13:50
Data point term sent to Coder	System	22 Apr 2021 13:13:20
Coding entries removed.	Olivia Hapanowicz (b) (4) (b) (4)	22 Apr 2021 13:12:40
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:33:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:33:29
Data point term sent to Coder	System	18 Mar 2021 19:22:48
Coding entries removed.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:11
Coding entries removed.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:11
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:11
User entered 'MRNA-1273 Vaccine' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:11
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 18:29:31

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 18:29:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, PRODUCT: VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:26:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:26:04
Data point term sent to Coder	System	22 Jan 2021 18:25:29
User entered 'mRNA-1273'	Ethan Shotton (b) (4) (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 11:20:10
' (Site from DM).		
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	Olivia Hapanowicz (b) (4)	11 Mar 2021 13:29:01
' answered with 'corrected' (Site from DM).	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	11 Mar 2021 13:28:52
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	18 Feb 2021 16:39:53
' (Site from DM).		
User entered 'No (N)'	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17
	(b) (4)	

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:29:23
User closed query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 17:34:40
Query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	22 Apr 2021 13:12:56
Signature has been broken.	Olivia Hapanowicz (b) (4) (b) (4)	22 Apr 2021 13:12:40
User entered 'COVID-19' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	22 Apr 2021 13:12:40
User opened query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 18:01:30
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:11
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:11
User entered 'COVID-19 Prophylaxis' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:11
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:11
User entered 'Wellness'	Ethan Shotton (b) (4) (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '100'	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'ug (ug)'	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'once (ONCE)'	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Intramuscular (INTRAMUSCULAR)'	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'UN UNK 2021'	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '0'	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'No (N)'	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'UN UNK 2021'	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'No (N)'	Ethan Shotton (b) (4)	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	22 Jan 2021 18:25:17

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 13:14:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 13:14:50
Data point term sent to Coder	System	22 Apr 2021 13:14:24
Coding entries removed.	Olivia Hapanowicz (b) (4) (b) (4)	22 Apr 2021 13:13:27
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:33:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:33:30
Data point term sent to Coder	System	18 Mar 2021 19:22:48
Coding entries removed.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:28
Coding entries removed.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:28
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:28
User entered 'MRNA-1273 Vaccine' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:28
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 18:29:32

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 18:29:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, PRODUCT: VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 23:21:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 23:21:12
Data point term sent to Coder	System	22 Jan 2021 23:20:18
User entered 'mRNA-1273'	Ethan Shotton (b) (4) (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 11:20:15
' (Site from DM).		
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	Olivia Hapanowicz (b) (4)	11 Mar 2021 13:29:19
' answered with 'corrected' (Site from DM).	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	11 Mar 2021 13:29:10
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	18 Feb 2021 16:40:17
' (Site from DM).		
User entered 'No (N)'	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03
	(b) (4)	

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 15:29:23
User closed query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 17:34:45
Query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	22 Apr 2021 13:13:50
Signature has been broken.	Olivia Hapanowicz (b) (4) (b) (4)	22 Apr 2021 13:13:27
User entered 'COVID-19' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	22 Apr 2021 13:13:27
User opened query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 18:01:40
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:27:11
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:28
User entered 'COVID-19 Prophylaxis' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 19:22:28
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:16:11
User entered 'Wellness'	Ethan Shotton (b) (4) (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '100'	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'ug (ug)'	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'once (ONCE)'	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Intramuscular (INTRAMUSCULAR)'	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '22 Jan 2021'	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '0'	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'No (N)'	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '22 Jan 2021'	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'No (N)'	Ethan Shotton (b) (4)	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered empty.	System	22 Jan 2021 23:20:03

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:07:37

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:30:37
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:08:17

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '30 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Colonic Tumor Resection'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:31:35
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4)	05 Nov 2020 17:41:17
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 02:00:41
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	14 Oct 2020 19:09:31
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	14 Oct 2020 19:09:04
User entered 'Adverse Event (AE)'	Darrell O'Brien (b) (4)	14 Oct 2020 19:09:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty; reason for change Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:09:31
User entered 'SAE - Stage III Colon Cancer Diagnosis'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:07:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '30 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:10:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:07:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Ileostomy'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:10:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:07:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Adverse Event (AE)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:10:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:07:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:10:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:07:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '16 Oct 2020'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:17:48

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:07:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'MRI POWER-PORT (FOR CHEMOTHERAPY) Right subclavian.' reason for change: New Information	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:01:41
User entered 'MRI Power-port (for chemotherapy).'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:17:48

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:07:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Adverse Event (AE)'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:17:48

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:07:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:17:48

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:07:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '31 Aug 2020'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:59:52

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:07:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Colonoscopy'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:59:52

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:07:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Diagnostic (DIAGNOSTIC)'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:59:52

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:07:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:59:52

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:07:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '31 Aug 2020'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:00:18

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:07:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'EGD'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:00:18

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:07:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Diagnostic (DIAGNOSTIC)'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:00:18

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:07:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:00:18

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:07:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '22 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:01:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:07:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'CT Scan (Chest, Abd, Pelv) with contrast'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:01:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:07:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Diagnostic (DIAGNOSTIC)'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:01:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:07:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:01:04

US3342088

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:07:37

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '17 Sep 2020'	Eileen Euperio (b) (4)	25 Sep 2020 13:40:49

US3342088

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:07:37

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE,However, no data is recorded on 'End of Study / Study Discontinuation'form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:29:51
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE,However, no data is recorded on 'End of Study / Study Discontinuation'form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' answered with 'Per CRF guidelines, subject does not meet necessary criteria for study discontinuation. Subject has discontinued dosing, but is still participating in the study and attending all visits.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:29:29
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE,However, no data is recorded on 'End of Study / Study Discontinuation'form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:34:45
User entered 'SAE (specify) (SAE)'	Eileen Euperio (b) (4) (b) (4)	25 Sep 2020 13:40:49

US3342088

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:07:37

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)	27 Apr 2021 12:34:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User closed query 'Per CDM Re-Query: thank you for the update however, please consider recorded the record number (AE#1 or SAE#1, etc.) instead of AEID number.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 08:43:20
Query 'Per CDM Re-Query: thank you for the update however, please consider recorded the record number (AE#1 or SAE#1, etc.) instead of AEID number.' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 14:01:48
User entered 'AE #1' reason for change: New Information	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 14:01:44
User opened query 'Per CDM Re-Query: thank you for the update however, please consider recorded the record number (AE#1 or SAE#1, etc.) instead of AEID number.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:34:32
User closed query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:34:32
Query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:23:32
User entered 'USA-US203-2020-MRNA-1273-P301000001' reason for change: New Information	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:23:22
User opened query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:58:59
User entered 'colon cancer diagnosis'	Eileen Euperio (b) (4) (b) (4)	25 Sep 2020 13:40:49

US3342088

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:37

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered '22 Jan 2021'	Ethan Shotton (b) (4)	22 Jan 2021 17:53:04

US3342088

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:37

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)'	Ethan Shotton (b) (4)	22 Jan 2021 17:53:04

US3342088

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:37

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)	27 Apr 2021 12:34:14
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:27:11
Signature has been broken.	Ethan Shotton (b) (4)	18 Mar 2021 18:56:51
User entered 'SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF Site (MODERNA PRODUCT mRNA-1273)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	18 Mar 2021 18:56:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered 'SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE STUDY (MODERNA PRODUCT)'	Ethan Shotton (b) (4)	22 Jan 2021 17:53:04

US3342088

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:37

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	22 Jan 2021 17:53:04

US3342088

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:37

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	22 Jan 2021 17:53:04

US3342088

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:37

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	22 Jan 2021 17:53:04

US3342088

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:37

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
User entered empty.	Ethan Shotton (b) (4)	22 Jan 2021 17:53:04

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'USA-US203-2020-MRNA-1273-P301000001'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:45:05
User entered 'US' (non-conformant).	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered '4'	System	06 Nov 2020 16:42:04
User entered '3'	System	15 Oct 2020 13:02:27
User entered '2'	System	12 Oct 2020 15:10:29
User entered '1'	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'USA-US203-2020-MRNA-1273-P301000001'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:45:05
User entered 'US' (non-conformant).	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered '4'	System	06 Nov 2020 16:42:04
User entered '3'	System	15 Oct 2020 13:02:27
User entered '2'	System	12 Oct 2020 15:10:29
User entered '1'	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:07:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
User entered '18/Sep/2020 12:04'	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:07:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
User entered 'I'	(b) (4), (b) (6)	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'USA-US203-2020-MRNA-1273-P301000001'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:45:05
User entered 'US' (non-conformant).	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered '4'	System	06 Nov 2020 16:42:04
User entered '3'	System	15 Oct 2020 13:02:27
User entered '2'	System	12 Oct 2020 15:10:29
User entered '1'	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:07:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 23:14:21
User entered '12/Oct/2020 11:10'	System	12 Oct 2020 15:10:29

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:07:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 23:14:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:02:18
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 15:10:29

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'USA-US203-2020-MRNA-1273-P301000001'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:45:05
User entered 'US' (non-conformant).	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered '4'	System	06 Nov 2020 16:42:04
User entered '3'	System	15 Oct 2020 13:02:27
User entered '2'	System	12 Oct 2020 15:10:29
User entered '1'	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:07:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 23:14:21
User entered '15/Oct/2020 09:02'	System	15 Oct 2020 13:02:27

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:07:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 23:14:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:41:50
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 13:02:27

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'USA-US203-2020-MRNA-1273-P301000001'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:45:05
User entered 'US' (non-conformant).	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User entered '4'	System	06 Nov 2020 16:42:04
User entered '3'	System	15 Oct 2020 13:02:27
User entered '2'	System	12 Oct 2020 15:10:29
User entered '1'	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:07:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 23:14:21
User entered '06/Nov/2020 11:41'	System	06 Nov 2020 16:42:04

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:07:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:29:23
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:16:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 23:14:21
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 16:42:04