

US3222296 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:05:58

All time stamps listed in this document are displayed in GMT

US3222296

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 14:36:19

Generated On: 09 Jun 2021 16:05:58

[Participant ID](#)

US3222296

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

US3222296

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 23 AUG 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
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) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Date of Informed Consent (*dd MMM yyyy*) 23 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3222296

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 14:37:12

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:58

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:58

Condition	
Start date (dd MMM yyyy)	
Start date completely unknown	
Condition ongoing at study entry	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 14:37:12

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:20 (24 HR)
Vital Signs Date and Time (derived)	23 AUG 2020 14:20
Height (<i>xxx.x</i>)	161.3 cm
Weight (<i>xxx.x</i>)	55.5 kg
BMI (<i>xxx.x</i>)	21.33164 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	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) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

23 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) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Date of assessment (*dd MMM yyyy*) 23 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*) UN UNK 2001

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 14:37:12

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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

COURT REPORTER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 14:37:12

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 23 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

What was the date of randomization? (dd MMM yyyy) 23 AUG 2020

What was the participant's randomization number? 107607

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) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

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) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

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 (<i>dd MMM yyyy</i>)	23 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:30 (24 HR)
Vital Signs Date and Time (derived)	23 AUG 2020 14:30
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:36 (24 HR)
Vital Signs Date and Time (derived)	23 AUG 2020 15:36
Temperature (<i>xxx.x</i>)	36.3 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

23 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

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) 23 AUG 2020

What was the treatment time? (00:00-23:59) 15:01 (24 HR)

Treatment Date and Time (derived) 23 AUG 2020 15:01

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) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 23 AUG 2020

Collection time (*00:00-23:59*) 14:50 (24 HR)

Collection date and time (derived) 23 AUG 2020 14:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Collection date (<i>dd MMM yyyy</i>)			23 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:51	23 AUG 2020 14:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

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 16:05:58

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 98.4 °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 23 AUG 2020 16:46

PC Open Date & Time 23 AUG 2020 15:21

PC Close Date & Time 23 AUG 2020 17:51

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	24 AUG 2020 06:34
PC Open Date & Time	23 AUG 2020 18:46
PC Close Date & Time	24 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 24 AUG 2020 12:00
PC Close Date & Time 25 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 AUG 2020 21:40
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 AUG 2020 23:06
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 AUG 2020 22:41
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 AUG 2020 19:57
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 AUG 2020 06:37
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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	23 AUG 2020 16:46
PC Open Date & Time	23 AUG 2020 15:21
PC Close Date & Time	23 AUG 2020 17:51

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

2

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

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

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 24 AUG 2020 06:38

PC Open Date & Time 23 AUG 2020 18:46

PC Close Date & Time 24 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 2

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

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

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

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

- Yes
- No

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

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

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

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 3

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	25 AUG 2020 21:40
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

26 AUG 2020 23:06

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 5

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

27 AUG 2020 22:42

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 6

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

28 AUG 2020 19:58

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 7

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

30 AUG 2020 06:38

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

No
Yes

PC Time stamp	23 AUG 2020 16:47
PC Open Date & Time	23 AUG 2020 15:21
PC Close Date & Time	23 AUG 2020 17:51

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

No
Yes

PC Time stamp	24 AUG 2020 06:39
PC Open Date & Time	23 AUG 2020 18:46
PC Close Date & Time	24 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

Yes

PC Time stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

	Yes <input type="checkbox"/>
PC Time stamp	25 AUG 2020 21:41
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

	Yes <input type="checkbox"/>
PC Time stamp	26 AUG 2020 23:07
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

	Yes <input type="checkbox"/>
PC Time stamp	27 AUG 2020 22:42
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

	Yes <input type="checkbox"/>
PC Time stamp	28 AUG 2020 19:58
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

	Yes <input type="checkbox"/>
PC Time stamp	30 AUG 2020 06:38
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3222296

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222296

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 7 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3222296

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222296

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3222296

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222296

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

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 (<i>dd MMM yyyy</i>)	22 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:10 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 08:10
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

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 (<i>dd MMM yyyy</i>)	22 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:35 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 09:35
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3222296

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

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.

US3222296

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 08:55 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 08:55

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

US3222296

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	22 SEP 2020
Collection time (<i>00:00-23:59</i>)	08:44 (24 HR)
Collection date and time (derived)	22 SEP 2020 08:44

US3222296

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Collection date (<i>dd MMM yyyy</i>)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:46	22 SEP 2020 08:46
Nasopharyngeal Swab 2	No		

US3222296

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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 98.6 °F

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

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

PC Time Stamp 22 SEP 2020 09:44

PC Open Date & Time 22 SEP 2020 09:15

PC Close Date & Time 22 SEP 2020 11:45

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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 99.1 °F

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

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

PC Time Stamp 23 SEP 2020 05:20
PC Open Date & Time 22 SEP 2020 12:40
PC Close Date & Time 23 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 SEP 2020 08:58
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 SEP 2020 06:49
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 SEP 2020 07:45
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 26 SEP 2020 12:00
PC Close Date & Time 27 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 SEP 2020 12:17
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	29 SEP 2020 06:05
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

22 SEP 2020 09:45

PC Open Date & Time

22 SEP 2020 09:15

PC Close Date & Time

22 SEP 2020 11:45

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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 23 SEP 2020 05:20

PC Open Date & Time 22 SEP 2020 12:40

PC Close Date & Time 23 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 2

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

24 SEP 2020 08:58

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 3

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

25 SEP 2020 06:49

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 4

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	26 SEP 2020 07:45
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 5

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

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

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

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

- Yes
- No

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

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

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

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 6

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

27 SEP 2020 12:17

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 7

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

29 SEP 2020 06:05

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

No

Yes

PC Time stamp	22 SEP 2020 09:45
PC Open Date & Time	22 SEP 2020 09:15
PC Close Date & Time	22 SEP 2020 11:45

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

No

Yes

PC Time stamp	23 SEP 2020 05:21
PC Open Date & Time	22 SEP 2020 12:40
PC Close Date & Time	23 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 08:58
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

	Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 06:50
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 07:46
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

Yes

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

	Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 12:18
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

	Yes <input type="checkbox"/>
PC Time stamp	29 SEP 2020 06:05
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3222296

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3222296

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222296

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 6 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3222296

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222296

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3222296

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222296

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 20 OCT 2020

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

Folder OID VISIT3

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222296

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

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.

US3222296

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 20 OCT 2020

Collection time (*00:00-23:59*) 09:15 (24 HR)

Collection date and time (derived) 20 OCT 2020 09:15

US3222296

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:12

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 26 OCT 2020 00:32:43

Patient Cloud Open Date & Time 23 OCT 2020 00:01

Patient Cloud Close Date & Time 27 OCT 2020 23:59

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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 01 NOV 2020 09:32:22

Patient Cloud Open Date & Time 30 OCT 2020 00:01

Patient Cloud Close Date & Time 03 NOV 2020 23:59

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT DAY 78

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) False

Chills False

Cough True

Shortness of breath True

Difficulty breathing True

Fatigue False

Muscle aches False

Body aches False

Headache False

New loss of taste False

New loss of smell False

Sore throat False

Congestion False

Runny nose False

Nausea False

Vomiting False

Diarrhea False

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

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 08 NOV 2020 21:53:38

Patient Cloud Open Date & Time 06 NOV 2020 00:01

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US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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 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"/>

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 89

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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

Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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 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	24 NOV 2020 06:04:30
Patient Cloud Open Date & Time	24 NOV 2020 00:01
Patient Cloud Close Date & Time	28 NOV 2020 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No
Yes

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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](#) 01 DEC 2020 00:01

[Patient Cloud Close Date & Time](#) 05 DEC 2020 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 110

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No Yes

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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	08 DEC 2020 00:01
Patient Cloud Close Date & Time	12 DEC 2020 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>
Date and time of submission	15 DEC 2020 10:58:32
Patient Cloud Open Date & Time	15 DEC 2020 00:01
Patient Cloud Close Date & Time	19 DEC 2020 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 124

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

No

Yes

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

No

Yes

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

Date and time of submission 24 DEC 2020 16:41:18

Patient Cloud Open Date & Time 22 DEC 2020 00:01

Patient Cloud Close Date & Time 26 DEC 2020 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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 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	29 DEC 2020 03:50:53
Patient Cloud Open Date & Time	29 DEC 2020 00:01
Patient Cloud Close Date & Time	02 JAN 2021 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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 <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	05 JAN 2021 19:13:53
Patient Cloud Open Date & Time	05 JAN 2021 00:01
Patient Cloud Close Date & Time	09 JAN 2021 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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 <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	13 JAN 2021 12:02:51
Patient Cloud Open Date & Time	12 JAN 2021 00:01
Patient Cloud Close Date & Time	16 JAN 2021 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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 <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	19 JAN 2021 19:49:59
Patient Cloud Open Date & Time	19 JAN 2021 00:01
Patient Cloud Close Date & Time	23 JAN 2021 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No Yes

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No Yes

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

Date and time of submission 28 JAN 2021 07:06:56

Patient Cloud Open Date & Time 26 JAN 2021 00:01

Patient Cloud Close Date & Time 30 JAN 2021 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>
Date and time of submission	02 FEB 2021 00:03:40
Patient Cloud Open Date & Time	02 FEB 2021 00:01
Patient Cloud Close Date & Time	06 FEB 2021 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 09 FEB 2021 04:13:03

Patient Cloud Open Date & Time 09 FEB 2021 00:01

Patient Cloud Close Date & Time 13 FEB 2021 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 FEB 2021 12:01:00
Patient Cloud Open Date & Time	16 FEB 2021 00:01
Patient Cloud Close Date & Time	20 FEB 2021 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>
Date and time of submission	23 FEB 2021 12:55:16
Patient Cloud Open Date & Time	23 FEB 2021 00:01
Patient Cloud Close Date & Time	27 FEB 2021 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	02 MAR 2021 08:20:54
Patient Cloud Open Date & Time	02 MAR 2021 00:01
Patient Cloud Close Date & Time	06 MAR 2021 23:59

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	09 MAR 2021 05:19:30
Patient Cloud Open Date & Time	09 MAR 2021 00:01
Patient Cloud Close Date & Time	13 MAR 2021 23:59

US3222296

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:05:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 08:21:02

US3222296

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 15 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3222296

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222296

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3222296

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222296

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 21 JAN 2021

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

Comments TRIED 3 ATTEMPTS AT
DIFFERENT TIMES AND LEFT
VOICEMAIL WITH NO
CALLBACK OR ANSWER.

If Contact Not Made, please provide Comments

US3222296

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222296

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:04:47

Generated On: 09 Jun 2021 16:05:58

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments _____

US3222296

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:04:47

Generated On: 09 Jun 2021 16:05:58

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3222296

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:04:47

Generated On: 09 Jun 2021 16:05:58

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT4

US3222296

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:58

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"/>

US3222296

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:05:58

Generate Next COVID-19 Assessment

Yes

No

US3222296

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

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 FEB 2021

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

Folder OID UNBLND_DECIDE

US3222296

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Date of updated informed consent (*dd MMM yyyy*) 12 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes
No

Under what version of the Protocol was the Participant unblinded? Amendment 5
Amendment 6 or later

Date of unblinding (*dd MMM yyyy*) 12 FEB 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3222296

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 FEB 2021

Collection time (*00:00-23:59*) 11:20 (24 HR)

Collection date and time (derived) 12 FEB 2021 11:20

US3222296

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 FEB 2021

Collection time (*00:00 - 23:59*) 11:23

Collection Date and Time (derived) 12 FEB 2021 11:23

US3222296

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

AEID	
Adverse event	PNEUMONIA
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)	23 SEP 2020
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	23 SEP 2020 00:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 OCT 2020
End time (00:00-23:59)	23:59 (24 HR)
AE End Date and Time (derived)	20 OCT 2020 23:59
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" 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"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

Congenital anomaly or birth defect	False
Other medically important event	False
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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" 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	ON 04/OCT/2020 PATIENT HAD A CT SCAN WHICH CONFIRMED DOUBLE PNEUMONIA. THE CT ALSO SHOWED A MASS ON HER LUNG WHICH SHE WILL HAVE A BIOPSY AND SHE WILL THEN CONTACT THE SITE WITH THEIR FINDINGS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

Admitted to ICU Derived (CSA Programming Field Only)

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

AEID	USA-US104-2021-MRNA-1273-P30 1000008
Adverse event	INVASIVE THYMOMA
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)	14 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" 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	True
Hospital Admission Date (dd MMM yyyy)	14 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	31 JAN 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	4

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EAB) (1725)

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US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" 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	

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

SUBJECT HAD PROCEDURE TO
HAVE ROBOTIC DIAPHRAGM
PLICATION AND THE
PROCEDURE KNICKED HER
SPLEEN WHICH CAUSED HER
TO HAVE A HEMATOMA OF
HER SPLEEN AND CAUSED HER
TO BE PLACED IN ICU FOR 4
OUT OF THE 8.
SARS COV2 COVID-19 PCR
NEGATIVE.
SHE WAS HOSPITALIZED.
MEDICAL RECORDS REQUEST
WAS SENT.

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)	1

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

AEID	USA-US104-2021-MRNA-1273-P30 1000009
Adverse event	NOROVIRUS
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)	31 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 FEB 2021
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	True
Hospital Admission Date (dd MMM yyyy)	31 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	04 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

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

Narrative PT STATED SHE WENT TO ADVENTHEALTH IN FLAGLER FOR VIRAL SYMPTOMS AND WAS IN HOSP FROM JAN 31 TO FEB 4. WILL REQUEST MEDICAL RECORDS TODAY

Serious Adverse Event Derived (CSA Programming Field Only) 1

Medically Attended AE Derived (CSA Programming Field Only) 1

Admitted to ICU Derived (CSA Programming Field Only) 0

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

AEID	USA-US104-2021-MRNA-1273-P30 1000017
Adverse event	INVASIVE THYMOMA
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)	04 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" 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	True
Hospital Admission Date (dd MMM yyyy)	04 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	11 DEC 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	4

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
 Related
 Not Applicable

Relationship to Study Procedure Not Related
 Related
 Not Applicable

Action taken with investigational product None
 Dose Delayed
 Investigational Product
 Withdrawn
 Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure True

Outcome Fatal
 Not Recovered/Not Resolved
 Recovered/Resolved
 Recovered/Resolved with Sequelae
 Recovering/Resolving
 Unknown

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

Narrative INVASIVE THYMOMA S/P THYMECTOMY WITH PARTIAL LEFT LOBECTOMY ON 12/4/20, CLOSE HEMATOMA OF SPLEEN SECONDARY TO RECENT SURGERY, ELEVATED HEMIDIAPHRAGM SECONDARY TO PHRENIC NERVE RESECTION DURING THYMECTOMY

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

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)	1

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

AEID	
Adverse event	MACULOPAPULAR RASH
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)	11 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <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 type="radio"/> No <input checked="" 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"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

Congenital anomaly or birth defect	False
Other medically important event	False
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 type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" 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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 20 Feb 2021 14:37:11

Generated On: 09 Jun 2021 16:05:58

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

Yes

No

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

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Name of Medication AMOXICILLIN

Prophylaxis Yes
No

Indication PNEUMONIA

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

	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*) 23 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 29 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Name of Medication ZITHROMAX

Prophylaxis Yes
No

Indication PNEUMONIA

Dose per administration 250

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

TAKE TWO PILLS DAY ONE
500MG DAY 2-5 TAKE ONE PILL
250MG

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

	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) 23 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 27 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Name of Medication METAPROLOL

Prophylaxis Yes
No

Indication HTN

Dose per administration 0.125

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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US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

	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*) 12 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Name of Medication PREDNISONE

Prophylaxis Yes
No

Indication AE # 5
MACULOPAPULAR

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

DOSE PACK DECREASING
DOSAGE OVER 6 DAYS

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

	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) 11 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 17 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Name of Medication TRIAMCINOLONE

Prophylaxis Yes
No

Indication AE # 5
MACULOPAPULAR

Dose per administration 0.025%

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify TOPICAL CREAM

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

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

	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)	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 NOV 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Name of Medication OXYCODONE

Prophylaxis Yes
No

Indication AE 2
INVASIVE THYMOMA

Dose per administration 325/5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

	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) 31 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Name of Medication OXYBUTYNIN

Prophylaxis Yes
No

Indication OVERACTIVE BLADDER

Dose per administration 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

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*) 31 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Name of Medication VENLAFAXINE

Prophylaxis Yes
No

Indication ANXIETY

Dose per administration 75

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

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

	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*) 31 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Name of Medication ZOLOFT

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

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*) 31 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 OCT 2020	CT CHEST	Diagnostic	
31 JAN 2021	THYMECTOMY	Adverse Event	
31 JAN 2021	CT ABDOMEN AND PELVIS	Adverse Event	

US3222296

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:05:58

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

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

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

US3222296

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 26 Apr 2021 14:04:46

Generated On: 09 Jun 2021 16:05:58

Date of study discontinuation/completion (dd MMM yyyy) 12 FEB 2021

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by participant (specify)

Other

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

SUBJECTS HAS MUCH TO
CONTEND WITH HER MEDICAL
HISTORY AND DOESNT WANT
TO CONTINUE IN THE TRIAL

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes

No

Unknown

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000008
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000008
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/FEB/2021 13:42
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

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000008
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	06/APR/2021 12:47
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

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P30 1000008
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/APR/2021 10:12
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

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000008
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/APR/2021 13:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000008
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/APR/2021 11:21
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

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000008
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	28/APR/2021 07:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000009
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000009
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/FEB/2021 13:44
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

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000009
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/APR/2021 13:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000009
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/APR/2021 13:19
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

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000009
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	27/APR/2021 14:43
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

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P30 1000017
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000017
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/APR/2021 14:13
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

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:13:04

Generated On: 09 Jun 2021 16:05:58

SAEID	USA-US104-2021-MRNA-1273-P301000017
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 checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	26/APR/2021 16:08
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.	<input checked="" type="checkbox"/> True

Audit

US3222296 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222296

Form: Participant Creation

Generated On: 09 Jun 2021 16:05:58

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:36:19
User entered 'US3222296'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 18:39:11

US3222296

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	23 Aug 2020 19:10:06

US3222296

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 18:39:12

US3222296

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[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 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	23 Aug 2020 19:10:06

US3222296

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered 'SCRN'	System	23 Aug 2020 19:10:06

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered (b) (6) 1960'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 18:39:13

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered '60'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered 'YEARS'	System	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered '60'	System	23 Aug 2020 19:10:17

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered 'Female (F)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered '1'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered '0'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered '0'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered '0'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered '0'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered '0'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered empty.	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered '0'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:58

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:35:18
User entered '0'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:02:31

US3222296

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:58

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Aug 2020'	Jennifer Dittman (b) (4)	23 Aug 2020 19:10:17

US3222296

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered 'Aug 2020'	System	23 Aug 2020 19:10:17

US3222296

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered '2020'	System	23 Aug 2020 19:10:17

US3222296

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:58

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Amendment 2 (2)'	Jennifer Dittman (b) (4)	23 Aug 2020 19:10:17

US3222296

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	23 Aug 2020 19:10:17

US3222296

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:58

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Jennifer Dittman (b) (4)	23 Aug 2020 19:10:17
	(b) (4)	

US3222296

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	Jennifer Dittman (b) (4)	23 Aug 2020 19:10:17

US3222296

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	Jennifer Dittman (b) (4)	23 Aug 2020 19:10:17

US3222296

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 18:39:12

US3222296

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered '1'	System	23 Aug 2020 19:10:22

US3222296

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Jennifer Dittman (b) (4)	23 Aug 2020 19:10:22

US3222296

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:05:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:03:33

US3222296

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:58

[Condition](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User closed query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	27 Oct 2020 20:01:08
Query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'THIS DATA IS REFLECTED ON THE CHILDBEARING POTENTIAL PAGE. PLEASE REVIEW AND REMOVE QUERY.' (Site from DM).	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:04:39
User opened query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 17:46:59
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:05:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:05:35
Data point term sent to Coder	System	24 Aug 2020 13:04:42
User entered 'Postmenopausal'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:04:21

US3222296

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'un UNK 2001'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:04:21

US3222296

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:58

Start date completely unknown

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '0'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:04:21

US3222296

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:04:21

US3222296

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:04:21
	(b) (4)	

US3222296

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '0'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:04:21
	(b) (4)	

US3222296

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered 'Jan 2001'	System	24 Aug 2020 13:04:21

US3222296

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:58

Start Year (derived)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered '2001'	System	24 Aug 2020 13:04:21

US3222296

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered empty.	System	24 Aug 2020 13:04:21

US3222296

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered empty.	System	24 Aug 2020 13:04:21

US3222296

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:58

[Condition](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:58

Start Year (derived)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:17:49
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:58:45
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:10:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '14:20'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered '23 Aug 2020 14:20'	System	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '161.3' cm	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:06:20
DataPoint set to visible.	(b) (4) System	23 Aug 2020 19:10:22

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '55.5' kg	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:06:20
DataPoint set to visible.	(b) (4) System	23 Aug 2020 19:10:22

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
Amendment Manager: User entered '21.33164'	System	17 Sep 2020 00:20:32
User entered '21.3'	System	24 Aug 2020 13:06:20
DataPoint set to visible.	System	23 Aug 2020 19:10:22

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered 'kg/m2'	System	24 Aug 2020 13:06:20
DataPoint set to visible.	System	23 Aug 2020 19:10:22

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 20:02:49
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:05:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:05:07
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 15:35:51
User entered '36.1' C	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:05:07
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	20 Sep 2020 21:05:07
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 13:06:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Aug 2020 13:06:26
User entered 'Oral (Oral)' reason for change: Data Entry Error	Amber Vasquez (b) (4)	24 Aug 2020 13:06:26
User entered empty; reason for change: Data Entry Error	(b) (4)	24 Aug 2020 13:06:26
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 13:06:20
User entered empty.	Amber Vasquez (b) (4)	24 Aug 2020 13:06:20
	(b) (4)	

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:05:07
User entered '76'	Albert Garcia (b) (4)	24 Aug 2020 13:06:20
	(b) (4)	

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered 'bpm'	System	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:05:07
User entered '18'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered 'breaths/min'	System	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:05:07
User entered '139'	Albert Garcia (b) (4)	24 Aug 2020 13:06:20
	(b) (4)	

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered 'mmHg'	System	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:05:07
User entered '93'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User entered 'mmHg'	System	24 Aug 2020 13:06:20

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56

US3222296

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:06:43

US3222296

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:06:43

US3222296

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:09

US3222296

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:09

US3222296

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:09

US3222296

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:58

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:09

US3222296

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:09

US3222296

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:58

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '0'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:09

US3222296

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'un UNK 2001'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:09

US3222296

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:58

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '0'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:09

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

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)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

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)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

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[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)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

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)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Court reporter'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '1'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '0'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

[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)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '0'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

[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)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '0'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

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)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '0'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '0'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '0'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered empty.	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:07:48

US3222296

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Jennifer Dittman (b) (4)	23 Aug 2020 19:10:38
	(b) (4)	

US3222296

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Aug 2020'	(b) (4) Jennifer Dittman (b) (4)	23 Aug 2020 19:10:38
	(b) (4)	

US3222296

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Clinic (Clinic)'	(b) (4) Jennifer Dittman (b) (4) (b) (4)	23 Aug 2020 19:10:38

US3222296

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'VISIT1'	System	23 Aug 2020 19:10:38

US3222296

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 18:49:14

US3222296

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '107607'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 18:49:14

US3222296

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 18:49:14

US3222296

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:58

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)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User closed query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:25:19
Query ' PER CDM: Please complete this section of the form' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:03:45
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:03:39
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:33:01

US3222296

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:58

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)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:03:39

US3222296

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:03:39

US3222296

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:58

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:03:39

US3222296

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:03:39

US3222296

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	20 Sep 2020 21:03:39
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:39:31
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:23:09

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:03:24
User entered '161.3' cm	Albert Garcia (b) (4)	24 Aug 2020 13:09:13
	(b) (4)	
	Amber Vasquez (b) (4)	
	(b) (4)	

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:03:24
User entered '55.5' kg	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:03:24
User entered '161.3' cm	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:03:24
User entered '55.5' kg	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '14:30'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '23 Aug 2020 14:30'	System	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '36.5' C	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '75'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'bpm'	System	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '18'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'breaths/min'	System	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '126'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'mmHg'	System	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '91'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'mmHg'	System	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:03:24
User entered '161.3' cm	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:03:24
User entered '55.5' kg	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '15:36'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '23 Aug 2020 15:36'	System	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '36.3' C	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '80'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'bpm'	System	24 Aug 2020 13:09:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '18'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'breaths/min'	System	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '114'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'mmHg'	System	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '88'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'mmHg'	System	24 Aug 2020 13:09:13

US3222296

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:10:16

US3222296

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:10:16

US3222296

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Jennifer Dittman (b) (4)	23 Aug 2020 19:11:19
	(b) (4)	

US3222296

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Jennifer Dittman (b) (4)	23 Aug 2020 19:11:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	Jennifer Dittman (b) (4)	23 Aug 2020 19:11:19

US3222296

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'MRNA-1273 OR PLACEBO'	System	23 Aug 2020 19:11:19

US3222296

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Aug 2020'	(b) (4) Jennifer Dittman (b) (4)	23 Aug 2020 19:11:19
	(b) (4)	

US3222296

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '15:01'	(b) (4) Jennifer Dittman (b) (4)	23 Aug 2020 19:11:19
	(b) (4)	

US3222296

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '23 Aug 2020 15:01'	System	23 Aug 2020 19:11:19

US3222296

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) Jennifer Dittman (b) (4)	23 Aug 2020 19:11:19
	(b) (4)	

US3222296

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'ONCE'	System	23 Aug 2020 19:11:19

US3222296

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'INTRAMUSCULAR'	System	23 Aug 2020 19:11:19

US3222296

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:10:41

US3222296

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:10:41

US3222296

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '14:50'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:10:41

US3222296

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '23 Aug 2020 14:50'	System	24 Aug 2020 13:10:41

US3222296

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:11:05

US3222296

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:11:05

US3222296

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:11:05

US3222296

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '14:51'	(b) (4) Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:11:05

US3222296

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '23 Aug 2020 14:51'	System	24 Aug 2020 13:11:05

US3222296

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:11:05

US3222296

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:11:30
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 13:11:05

US3222296

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	24 Aug 2020 13:11:30
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	24 Aug 2020 13:11:30
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	24 Aug 2020 13:11:05
User entered empty.	Amber Vasquez (b) (4)	24 Aug 2020 13:11:05
	(b) (4)	

US3222296

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered empty.	System	24 Aug 2020 13:11:05

US3222296

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	24 Aug 2020 13:11:41

US3222296

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '1'	System	24 Aug 2020 13:11:41

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:45:41', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '9d4e3ad2-0c8d-4ae7-bdd8-e6d1efcd773c' User entered 'Yes (Y)'	System	23 Aug 2020 20:46:04
	System	23 Aug 2020 20:46:04

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:45:50', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '9d4e3ad2-0c8d-4ae7-bdd8-e6d1efcd773c' User entered '98.4'	System	23 Aug 2020 20:46:04
	System	23 Aug 2020 20:46:04

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:45:53', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '9d4e3ad2-0c8d-4ae7-bdd8-e6d1efcd773c' User entered 'No (N)'	System	23 Aug 2020 20:46:04
	System	23 Aug 2020 20:46:04

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:46:02', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '9d4e3ad2-0c8d-4ae7-bdd8-e6d1efcd773c' User entered '23 Aug 2020 16:46'	System	23 Aug 2020 20:46:04
	System	23 Aug 2020 20:46:04

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Aug 2020 15:21'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Aug 2020 17:51'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:34:37', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '7673f101-f599-4977-a776-69184d606ae1' User entered 'Yes (Y)'	System	24 Aug 2020 10:34:56
	System	24 Aug 2020 10:34:56

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:34:46', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '7673f101-f599-4977-a776-69184d606ae1' User entered '97.9'	System	24 Aug 2020 10:34:56
	System	24 Aug 2020 10:34:56

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:34:50', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '7673f101-f599-4977-a776-69184d606ae1' User entered 'No (N)'	System	24 Aug 2020 10:34:56
	System	24 Aug 2020 10:34:56

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:34:55', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '7673f101-f599-4977-a776-69184d606ae1' User entered '24 Aug 2020 06:34'	System	24 Aug 2020 10:34:56
	System	24 Aug 2020 10:34:56

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Aug 2020 18:46'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 2'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 3'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:40:11', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'e6d3a2c9-6a2d-45f7-ba1a-a1a02594178f' User entered 'Yes (Y)'	System	26 Aug 2020 01:40:31
	System	26 Aug 2020 01:40:31

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:40:16', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'e6d3a2c9-6a2d-45f7-ba1a-a1a02594178f' User entered '98.8'	System	26 Aug 2020 01:40:31
	System	26 Aug 2020 01:40:31

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:40:22', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'e6d3a2c9-6a2d-45f7-ba1a-a1a02594178f' User entered 'No (N)'	System	26 Aug 2020 01:40:31
	System	26 Aug 2020 01:40:31

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:40:27', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'e6d3a2c9-6a2d-45f7-ba1a-a1a02594178f' User entered '25 Aug 2020 21:40'	System	26 Aug 2020 01:40:31
	System	26 Aug 2020 01:40:31

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 4'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:05:31', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '1fc524ca-af3f-4c6e-b50b-d3313c0a7bba' User entered 'Yes (Y)'	System	27 Aug 2020 03:06:23
	System	27 Aug 2020 03:06:23

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:06:11', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '1fc524ca-af3f-4c6e-b50b-d3313c0a7bba' User entered '97.6'	System	27 Aug 2020 03:06:23
	System	27 Aug 2020 03:06:23

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:06:15', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '1fc524ca-af3f-4c6e-b50b-d3313c0a7bba' User entered 'No (N)'	System	27 Aug 2020 03:06:23
	System	27 Aug 2020 03:06:23

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:06:21', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '1fc524ca-af3f-4c6e-b50b-d3313c0a7bba' User entered '26 Aug 2020 23:06'	System	27 Aug 2020 03:06:23
	System	27 Aug 2020 03:06:23

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 5'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:39:55', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8a00699b-bc0b-41bc-94b1-493aa71c4de5' User entered 'Yes (Y)'	System	28 Aug 2020 02:41:47
	System	28 Aug 2020 02:41:47

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:41:37', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8a00699b-bc0b-41bc-94b1-493aa71c4de5' User entered '97.4'	System	28 Aug 2020 02:41:47
	System	28 Aug 2020 02:41:47

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:41:41', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8a00699b-bc0b-41bc-94b1-493aa71c4de5' User entered 'No (N)'	System	28 Aug 2020 02:41:47
	System	28 Aug 2020 02:41:47

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:41:44', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8a00699b-bc0b-41bc-94b1-493aa71c4de5' User entered '27 Aug 2020 22:41'	System	28 Aug 2020 02:41:47
	System	28 Aug 2020 02:41:47

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 6'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:57:44', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '60cedaa3-a7f2-4e99-a1d1-f64e1a268170' User entered 'Yes (Y)'	System	28 Aug 2020 23:57:59
	System	28 Aug 2020 23:57:59

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:57:50', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '60cedaa3-a7f2-4e99-a1d1-f64e1a268170' User entered '97.9'	System	28 Aug 2020 23:57:59
	System	28 Aug 2020 23:57:59

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:57:53', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '60cedaa3-a7f2-4e99-a1d1-f64e1a268170' User entered 'No (N)'	System	28 Aug 2020 23:57:59
	System	28 Aug 2020 23:57:59

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:57:58', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '60cedaa3-a7f2-4e99-a1d1-f64e1a268170' User entered '28 Aug 2020 19:57'	System	28 Aug 2020 23:57:59
	System	28 Aug 2020 23:57:59

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 7'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:37:33', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '35f5f2f5-a3bf-40db-a713-5a1b22ad950a' User entered 'Yes (Y)'	System	30 Aug 2020 10:37:54
	System	30 Aug 2020 10:37:54

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:37:42', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '35f5f2f5-a3bf-40db-a713-5a1b22ad950a' User entered '97.6'	System	30 Aug 2020 10:37:54
	System	30 Aug 2020 10:37:54

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:37:47', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '35f5f2f5-a3bf-40db-a713-5a1b22ad950a'	System	30 Aug 2020 10:37:54
User entered 'No (N)'	System	30 Aug 2020 10:37:54

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:37:50', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '35f5f2f5-a3bf-40db-a713-5a1b22ad950a' User entered '30 Aug 2020 06:37'	System	30 Aug 2020 10:37:54
	System	30 Aug 2020 10:37:54

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:46:29', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'cd4f35af-a605-46fc-bdb7-6350613bde01'	System	23 Aug 2020 20:46:57
User entered 'None (1)'	System	23 Aug 2020 20:46:57

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:46:38', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'cd4f35af-a605-46fc-bdb7-6350613bde01' User entered 'No (N)'	System	23 Aug 2020 20:46:57
	System	23 Aug 2020 20:46:57

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:46:42', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'cd4f35af-a605-46fc-bdb7-6350613bde01' User entered 'No (N)'	System	23 Aug 2020 20:46:57
	System	23 Aug 2020 20:46:57

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:46:48', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'cd4f35af-a605-46fc-bdb7-6350613bde01'	System	23 Aug 2020 20:46:57
User entered 'None (1)'	System	23 Aug 2020 20:46:57

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:46:54', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'cd4f35af-a605-46fc-bdb7-6350613bde01' User entered '23 Aug 2020 16:46'	System	23 Aug 2020 20:46:57
	System	23 Aug 2020 20:46:57

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Aug 2020 15:21'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Aug 2020 17:51'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:35:07', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a1d2b7e2-fbe1-4970-a57b-595b1a695caa'	System	24 Aug 2020 10:38:55
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 10:38:55

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:35:18', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a1d2b7e2-fbe1-4970-a57b-595b1a695caa' User entered 'No (N)'	System	24 Aug 2020 10:38:55
	System	24 Aug 2020 10:38:55

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:35:27', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a1d2b7e2-fbe1-4970-a57b-595b1a695caa' User entered 'Yes (Y)'	System	24 Aug 2020 10:38:55
	System	24 Aug 2020 10:38:55

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:38:36', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a1d2b7e2-fbe1-4970-a57b-595b1a695caa' User entered '2'	System	24 Aug 2020 10:38:55
	System	24 Aug 2020 10:38:55

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:38:42', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a1d2b7e2-fbe1-4970-a57b-595b1a695caa' User entered 'None (1)'	System	24 Aug 2020 10:38:55
	System	24 Aug 2020 10:38:55

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:38:52', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a1d2b7e2-fbe1-4970-a57b-595b1a695caa' User entered '24 Aug 2020 06:38'	System	24 Aug 2020 10:38:55
	System	24 Aug 2020 10:38:55

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Aug 2020 18:46'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 2'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 3'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:40:36', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'fe4062e5-f4e5-4a3d-b339-5e6aaa3efa66'	System	26 Aug 2020 01:41:01
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 01:41:01

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:40:40', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'fe4062e5-f4e5-4a3d-b339-5e6aaa3efa66'	System	26 Aug 2020 01:41:01
User entered 'No (N)'	System	26 Aug 2020 01:41:01

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:40:46', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'fe4062e5-f4e5-4a3d-b339-5e6aaa3efa66' User entered 'No (N)'	System	26 Aug 2020 01:41:01
	System	26 Aug 2020 01:41:01

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:40:49', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'fe4062e5-f4e5-4a3d-b339-5e6aaa3efa66'	System	26 Aug 2020 01:41:01
User entered 'None (1)'	System	26 Aug 2020 01:41:01

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:40:54', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'fe4062e5-f4e5-4a3d-b339-5e6aaa3efa66' User entered '25 Aug 2020 21:40'	System	26 Aug 2020 01:41:01
	System	26 Aug 2020 01:41:01

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 4'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:06:28', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '495f7b67-c7e7-417f-9748-b5e77a4376bf'	System	27 Aug 2020 03:06:44
User entered 'None (1)'	System	27 Aug 2020 03:06:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:06:32', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '495f7b67-c7e7-417f-9748-b5e77a4376bf' User entered 'No (N)'	System	27 Aug 2020 03:06:44
	System	27 Aug 2020 03:06:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:06:35', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '495f7b67-c7e7-417f-9748-b5e77a4376bf' User entered 'No (N)'	System	27 Aug 2020 03:06:44
	System	27 Aug 2020 03:06:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:06:39', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '495f7b67-c7e7-417f-9748-b5e77a4376bf' User entered 'None (1)'	System	27 Aug 2020 03:06:44
	System	27 Aug 2020 03:06:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:06:42', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '495f7b67-c7e7-417f-9748-b5e77a4376bf' User entered '26 Aug 2020 23:06'	System	27 Aug 2020 03:06:44
	System	27 Aug 2020 03:06:44

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 5'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:41:50', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6eea6bb2-9aff-4bc2-9349-ea328ce54db8' User entered 'None (1)'	System	28 Aug 2020 02:42:13
	System	28 Aug 2020 02:42:13

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:41:55', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6eea6bb2-9aff-4bc2-9349-ea328ce54db8'	System	28 Aug 2020 02:42:13
User entered 'No (N)'	System	28 Aug 2020 02:42:13

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:41:59', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6eea6bb2-9aff-4bc2-9349-ea328ce54db8' User entered 'No (N)'	System	28 Aug 2020 02:42:13
	System	28 Aug 2020 02:42:13

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:42:06', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6eea6bb2-9aff-4bc2-9349-ea328ce54db8'	System	28 Aug 2020 02:42:13
User entered 'None (1)'	System	28 Aug 2020 02:42:13

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:42:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6eea6bb2-9aff-4bc2-9349-ea328ce54db8' User entered '27 Aug 2020 22:42'	System	28 Aug 2020 02:42:13
	System	28 Aug 2020 02:42:13

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 6'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:02', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'c06860f8-1cfe-4849-9553-c147f18671d2'	System	28 Aug 2020 23:58:17
User entered 'None (1)'	System	28 Aug 2020 23:58:17

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:06', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'c06860f8-1cfe-4849-9553-c147f18671d2'	System	28 Aug 2020 23:58:17
User entered 'No (N)'	System	28 Aug 2020 23:58:17

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:08', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'c06860f8-1cfe-4849-9553-c147f18671d2'	System	28 Aug 2020 23:58:17
User entered 'No (N)'	System	28 Aug 2020 23:58:17

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:11', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'c06860f8-1cfe-4849-9553-c147f18671d2'	System	28 Aug 2020 23:58:17
User entered 'None (1)'	System	28 Aug 2020 23:58:17

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:14', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'c06860f8-1cfe-4849-9553-c147f18671d2' User entered '28 Aug 2020 19:58'	System	28 Aug 2020 23:58:17
	System	28 Aug 2020 23:58:17

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 7'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:37:54', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'aa413883-90f8-47b8-ba10-9dd2576d53d7'	System	30 Aug 2020 10:38:10
User entered 'None (1)'	System	30 Aug 2020 10:38:10

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:37:58', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'aa413883-90f8-47b8-ba10-9dd2576d53d7'	System	30 Aug 2020 10:38:10
User entered 'No (N)'	System	30 Aug 2020 10:38:10

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:38:01', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'aa413883-90f8-47b8-ba10-9dd2576d53d7'	System	30 Aug 2020 10:38:10
User entered 'No (N)'	System	30 Aug 2020 10:38:10

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:38:04', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'aa413883-90f8-47b8-ba10-9dd2576d53d7'	System	30 Aug 2020 10:38:10
User entered 'None (1)'	System	30 Aug 2020 10:38:10

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:38:06', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'aa413883-90f8-47b8-ba10-9dd2576d53d7'	System	30 Aug 2020 10:38:10
User entered '30 Aug 2020 06:38'	System	30 Aug 2020 10:38:10

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:47:12', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'd1c1a63f-67bd-45ea-830a-98d4955bbfd6'	System	23 Aug 2020 20:47:43
User entered 'No interference with activity (1)'	System	23 Aug 2020 20:47:43

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:47:22', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'd1c1a63f-67bd-45ea-830a-98d4955bbfd6'	System	23 Aug 2020 20:47:43
User entered 'No interference with activity (1)'	System	23 Aug 2020 20:47:43

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:47:26', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'd1c1a63f-67bd-45ea-830a-98d4955bbfd6'	System	23 Aug 2020 20:47:43
User entered 'None (0)'	System	23 Aug 2020 20:47:43

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:47:28', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'd1c1a63f-67bd-45ea-830a-98d4955bbfd6' User entered 'None (0)'	System	23 Aug 2020 20:47:43
	System	23 Aug 2020 20:47:43

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:47:30', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'd1c1a63f-67bd-45ea-830a-98d4955bbfd6'	System	23 Aug 2020 20:47:43
User entered 'None (0)'	System	23 Aug 2020 20:47:43

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:47:32', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'd1c1a63f-67bd-45ea-830a-98d4955bbfd6' User entered 'None (0)'	System	23 Aug 2020 20:47:43
	System	23 Aug 2020 20:47:43

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:47:38', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'd1c1a63f-67bd-45ea-830a-98d4955bbfd6' User entered 'No (N)'	System	23 Aug 2020 20:47:43
	System	23 Aug 2020 20:47:43

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-23T16:47:41', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'd1c1a63f-67bd-45ea-830a-98d4955bbfd6' User entered '23 Aug 2020 16:47'	System	23 Aug 2020 20:47:43
	System	23 Aug 2020 20:47:43

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Aug 2020 15:21'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Aug 2020 17:51'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:38:58', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '72b7611e-b0c1-4776-876c-1b2a47c2584e' User entered 'None (0)'	System	24 Aug 2020 10:39:31
	System	24 Aug 2020 10:39:31

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:39:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '72b7611e-b0c1-4776-876c-1b2a47c2584e' User entered 'None (0)'	System	24 Aug 2020 10:39:31
	System	24 Aug 2020 10:39:31

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:39:12', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '72b7611e-b0c1-4776-876c-1b2a47c2584e' User entered 'None (0)'	System	24 Aug 2020 10:39:31
	System	24 Aug 2020 10:39:31

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:39:14', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '72b7611e-b0c1-4776-876c-1b2a47c2584e' User entered 'None (0)'	System	24 Aug 2020 10:39:31
	System	24 Aug 2020 10:39:31

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:39:16', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '72b7611e-b0c1-4776-876c-1b2a47c2584e' User entered 'None (0)'	System	24 Aug 2020 10:39:31
	System	24 Aug 2020 10:39:31

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:39:18', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '72b7611e-b0c1-4776-876c-1b2a47c2584e' User entered 'None (0)'	System	24 Aug 2020 10:39:31
	System	24 Aug 2020 10:39:31

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:39:25', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '72b7611e-b0c1-4776-876c-1b2a47c2584e' User entered 'No (N)'	System	24 Aug 2020 10:39:31
	System	24 Aug 2020 10:39:31

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-24T06:39:28', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '72b7611e-b0c1-4776-876c-1b2a47c2584e' User entered '24 Aug 2020 06:39'	System	24 Aug 2020 10:39:31
	System	24 Aug 2020 10:39:31

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Aug 2020 18:46'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 2'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 3'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:41:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '994221e5-3653-4715-b227-326cc812fdb4'	System	26 Aug 2020 01:41:41
User entered 'No interference with activity (1)'	System	26 Aug 2020 01:41:41

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:41:11', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '994221e5-3653-4715-b227-326cc812fdb4'	System	26 Aug 2020 01:41:41
User entered 'Some interference with activity (2)'	System	26 Aug 2020 01:41:41

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:41:17', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '994221e5-3653-4715-b227-326cc812fdb4'	System	26 Aug 2020 01:41:41
User entered 'No interference with activity (1)'	System	26 Aug 2020 01:41:41

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:41:21', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '994221e5-3653-4715-b227-326cc812fdb4' User entered 'None (0)'	System	26 Aug 2020 01:41:41
	System	26 Aug 2020 01:41:41

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:41:24', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '994221e5-3653-4715-b227-326cc812fdb4' User entered 'None (0)'	System	26 Aug 2020 01:41:41
	System	26 Aug 2020 01:41:41

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:41:27', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '994221e5-3653-4715-b227-326cc812fdb4' User entered 'None (0)'	System	26 Aug 2020 01:41:41
	System	26 Aug 2020 01:41:41

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:41:34', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '994221e5-3653-4715-b227-326cc812fdb4' User entered 'No (N)'	System	26 Aug 2020 01:41:41
	System	26 Aug 2020 01:41:41

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-25T21:41:39', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '994221e5-3653-4715-b227-326cc812fdb4' User entered '25 Aug 2020 21:41'	System	26 Aug 2020 01:41:41
	System	26 Aug 2020 01:41:41

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 4'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:06:51', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3e21b556-dfb6-48ba-85a2-32a3ec902db7' User entered 'None (0)'	System	27 Aug 2020 03:07:36
	System	27 Aug 2020 03:07:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:07:04', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3e21b556-dfb6-48ba-85a2-32a3ec902db7'	System	27 Aug 2020 03:07:36
User entered 'No interference with activity (1)'	System	27 Aug 2020 03:07:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:07:11', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3e21b556-dfb6-48ba-85a2-32a3ec902db7' User entered 'None (0)'	System	27 Aug 2020 03:07:36
	System	27 Aug 2020 03:07:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:07:15', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3e21b556-dfb6-48ba-85a2-32a3ec902db7' User entered 'None (0)'	System	27 Aug 2020 03:07:36
	System	27 Aug 2020 03:07:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:07:21', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3e21b556-dfb6-48ba-85a2-32a3ec902db7' User entered 'None (0)'	System	27 Aug 2020 03:07:36
	System	27 Aug 2020 03:07:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:07:24', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3e21b556-dfb6-48ba-85a2-32a3ec902db7' User entered 'None (0)'	System	27 Aug 2020 03:07:36
	System	27 Aug 2020 03:07:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:07:31', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3e21b556-dfb6-48ba-85a2-32a3ec902db7'	System	27 Aug 2020 03:07:36
User entered 'No (N)'	System	27 Aug 2020 03:07:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-26T23:07:35', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3e21b556-dfb6-48ba-85a2-32a3ec902db7' User entered '26 Aug 2020 23:07'	System	27 Aug 2020 03:07:36
	System	27 Aug 2020 03:07:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 5'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:42:14', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '086ff3cd-8e76-4993-a588-949494bf0460' User entered 'None (0)'	System	28 Aug 2020 02:42:39
	System	28 Aug 2020 02:42:39

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:42:17', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '086ff3cd-8e76-4993-a588-949494bf0460'	System	28 Aug 2020 02:42:39
User entered 'No interference with activity (1)'	System	28 Aug 2020 02:42:39

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:42:20', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '086ff3cd-8e76-4993-a588-949494bf0460' User entered 'None (0)'	System	28 Aug 2020 02:42:39
	System	28 Aug 2020 02:42:39

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:42:23', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '086ff3cd-8e76-4993-a588-949494bf0460' User entered 'None (0)'	System	28 Aug 2020 02:42:39
	System	28 Aug 2020 02:42:39

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:42:25', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '086ff3cd-8e76-4993-a588-949494bf0460' User entered 'None (0)'	System	28 Aug 2020 02:42:39
	System	28 Aug 2020 02:42:39

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:42:29', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '086ff3cd-8e76-4993-a588-949494bf0460'	System	28 Aug 2020 02:42:39
User entered 'No interference with activity (1)'	System	28 Aug 2020 02:42:39

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:42:35', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '086ff3cd-8e76-4993-a588-949494bf0460' User entered 'No (N)'	System	28 Aug 2020 02:42:39
	System	28 Aug 2020 02:42:39

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-27T22:42:37', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '086ff3cd-8e76-4993-a588-949494bf0460' User entered '27 Aug 2020 22:42'	System	28 Aug 2020 02:42:39
	System	28 Aug 2020 02:42:39

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 6'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:19', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f8ee3540-e977-452a-a915-42d5417ce8a6'	System	28 Aug 2020 23:58:36
User entered 'None (0)'	System	28 Aug 2020 23:58:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:22', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f8ee3540-e977-452a-a915-42d5417ce8a6'	System	28 Aug 2020 23:58:36
User entered 'None (0)'	System	28 Aug 2020 23:58:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:24', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f8ee3540-e977-452a-a915-42d5417ce8a6'	System	28 Aug 2020 23:58:36
User entered 'None (0)'	System	28 Aug 2020 23:58:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:26', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f8ee3540-e977-452a-a915-42d5417ce8a6'	System	28 Aug 2020 23:58:36
User entered 'None (0)'	System	28 Aug 2020 23:58:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:28', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f8ee3540-e977-452a-a915-42d5417ce8a6'	System	28 Aug 2020 23:58:36
User entered 'None (0)'	System	28 Aug 2020 23:58:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:30', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f8ee3540-e977-452a-a915-42d5417ce8a6' User entered 'None (0)'	System	28 Aug 2020 23:58:36
	System	28 Aug 2020 23:58:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:33', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f8ee3540-e977-452a-a915-42d5417ce8a6'	System	28 Aug 2020 23:58:36
User entered 'No (N)'	System	28 Aug 2020 23:58:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-28T19:58:35', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f8ee3540-e977-452a-a915-42d5417ce8a6' User entered '28 Aug 2020 19:58'	System	28 Aug 2020 23:58:36
	System	28 Aug 2020 23:58:36

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 7'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:38:11', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '518cd1b1-c54e-4e24-8e9b-ac8933c71949' User entered 'None (0)'	System	30 Aug 2020 10:38:32
	System	30 Aug 2020 10:38:32

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:38:13', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '518cd1b1-c54e-4e24-8e9b-ac8933c71949' User entered 'None (0)'	System	30 Aug 2020 10:38:32
	System	30 Aug 2020 10:38:32

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:38:15', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '518cd1b1-c54e-4e24-8e9b-ac8933c71949' User entered 'None (0)'	System	30 Aug 2020 10:38:32
	System	30 Aug 2020 10:38:32

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:38:17', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '518cd1b1-c54e-4e24-8e9b-ac8933c71949' User entered 'None (0)'	System	30 Aug 2020 10:38:32
	System	30 Aug 2020 10:38:32

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:38:20', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '518cd1b1-c54e-4e24-8e9b-ac8933c71949' User entered 'None (0)'	System	30 Aug 2020 10:38:32
	System	30 Aug 2020 10:38:32

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:38:21', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '518cd1b1-c54e-4e24-8e9b-ac8933c71949' User entered 'None (0)'	System	30 Aug 2020 10:38:32
	System	30 Aug 2020 10:38:32

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:38:25', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '518cd1b1-c54e-4e24-8e9b-ac8933c71949' User entered 'No (N)'	System	30 Aug 2020 10:38:32
	System	30 Aug 2020 10:38:32

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-08-30T06:38:27', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '518cd1b1-c54e-4e24-8e9b-ac8933c71949' User entered '30 Aug 2020 06:38'	System	30 Aug 2020 10:38:32
	System	30 Aug 2020 10:38:32

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 19:11:19

US3222296

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:41:22

US3222296

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Sep 2020 13:41:43
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	22 Sep 2020 13:41:43
User entered '31 Aug 2020' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	22 Sep 2020 13:41:43
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Sep 2020 13:41:22
User entered '7 Sep 2020'	Jennifer Dittman (b) (4) (b) (4)	22 Sep 2020 13:41:22

US3222296

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:41:22
	(b) (4)	

US3222296

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:41:22
	(b) (4)	

US3222296

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	22 Sep 2020 13:41:49

US3222296

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'I'	System	22 Sep 2020 13:41:49

US3222296

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:42:07
	(b) (4)	

US3222296

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '7 Sep 2020'	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:42:07
	(b) (4)	

US3222296

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:42:07

US3222296

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:42:07
	(b) (4)	

US3222296

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	22 Sep 2020 13:42:12

US3222296

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User entered '1'	System	22 Sep 2020 13:42:12

US3222296

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	22 Sep 2020 13:42:31

US3222296

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '14 Sep 2020'	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:42:31
	(b) (4)	

US3222296

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	22 Sep 2020 13:42:31

US3222296

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:42:31
	(b) (4)	

US3222296

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	22 Sep 2020 13:42:36

US3222296

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User entered '1'	System	22 Sep 2020 13:42:36

US3222296

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:42:51

US3222296

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '22 Sep 2020'	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:42:51
	(b) (4)	

US3222296

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Clinic (Clinic)'	(b) (4) Jennifer Dittman (b) (4) (b) (4)	22 Sep 2020 13:42:51

US3222296

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'VISIT2'	System	22 Sep 2020 13:42:51

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '22 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '08:10'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '22 Sep 2020 08:10'	System	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '37.0' C	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Oral (Oral)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered empty.	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '88'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'bpm'	System	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '17'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'breaths/min'	System	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '126'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'mmHg'	System	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '87'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'mmHg'	System	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '22 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '09:35'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '22 Sep 2020 09:35'	System	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '37.0' C	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Oral (Oral)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered empty.	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '85'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'bpm'	System	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '17'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'breaths/min'	System	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '107'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'mmHg'	System	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '82'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'mmHg'	System	16 Oct 2020 18:20:53

US3222296

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:02

US3222296

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Albert Garcia (b) (4)	16 Oct 2020 18:21:02

US3222296

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User closed query 'Per CDM: V2D29 visit was performed, Please complete VITAL SIGNS, PHYSICAL EXAMINATION IMMUNOGENICITY ASSESSMENT, CENTRAL LABORATORY - NASOPHARYNGEAL SWAB Pages.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:54:38
Query 'Per CDM: V2D29 visit was performed, Please complete VITAL SIGNS, PHYSICAL EXAMINATION IMMUNOGENICITY ASSESSMENT, CENTRAL LABORATORY - NASOPHARYNGEAL SWAB Pages.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:13
User opened query 'Per CDM: V2D29 visit was performed, Please complete VITAL SIGNS, PHYSICAL EXAMINATION IMMUNOGENICITY ASSESSMENT, CENTRAL LABORATORY - NASOPHARYNGEAL SWAB Pages.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 10:20:10
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	22 Sep 2020 13:43:18

US3222296

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:43:18
	(b) (4)	

US3222296

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

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)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	Jennifer Dittman (b) (4)	22 Sep 2020 13:43:18

US3222296

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 13:43:18

US3222296

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '22 Sep 2020'	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:43:18
	(b) (4)	

US3222296

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '08:55'	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:43:18

US3222296

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '22 Sep 2020 08:55'	System	22 Sep 2020 13:43:18

US3222296

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) Jennifer Dittman (b) (4)	22 Sep 2020 13:43:18

US3222296

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'ONCE'	System	22 Sep 2020 13:43:18

US3222296

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 13:43:18

US3222296

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:33

US3222296

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '22 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:33

US3222296

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '08:44'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:33

US3222296

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '22 Sep 2020 08:44'	System	16 Oct 2020 18:21:33

US3222296

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '22 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:47

US3222296

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:47

US3222296

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:47

US3222296

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '08:46'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:47

US3222296

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '22 Sep 2020 08:46'	System	16 Oct 2020 18:21:47

US3222296

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:47

US3222296

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:47

US3222296

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:47

US3222296

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered empty.	System	16 Oct 2020 18:21:47

US3222296

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:21:50

US3222296

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '1'	System	16 Oct 2020 18:21:50

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:44:38', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a6302be5-d81c-467d-92f7-e1c79fc68c27'	System	22 Sep 2020 13:44:58
User entered 'Yes (Y)'	System	22 Sep 2020 13:44:58

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:44:46', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a6302be5-d81c-467d-92f7-e1c79fc68c27'	System	22 Sep 2020 13:44:58
User entered '98.6'	System	22 Sep 2020 13:44:58

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:44:51', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a6302be5-d81c-467d-92f7-e1c79fc68c27'	System	22 Sep 2020 13:44:58
User entered 'No (N)'	System	22 Sep 2020 13:44:58

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:44:55', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a6302be5-d81c-467d-92f7-e1c79fc68c27' User entered '22 Sep 2020 09:44'	System	22 Sep 2020 13:44:58
	System	22 Sep 2020 13:44:58

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '22 Sep 2020 09:15'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '22 Sep 2020 11:45'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:20:08', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8abc91c9-253d-4c3c-bfb8-f67b77d09fdd' User entered 'Yes (Y)'	System	23 Sep 2020 09:20:24
	System	23 Sep 2020 09:20:24

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:20:12', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8abc91c9-253d-4c3c-bfb8-f67b77d09fdd' User entered '99.1'	System	23 Sep 2020 09:20:24
	System	23 Sep 2020 09:20:24

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:20:17', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8abc91c9-253d-4c3c-bfb8-f67b77d09fdd'	System	23 Sep 2020 09:20:24
User entered 'No (N)'	System	23 Sep 2020 09:20:24

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:20:21', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8abc91c9-253d-4c3c-bfb8-f67b77d09fdd' User entered '23 Sep 2020 05:20'	System	23 Sep 2020 09:20:24
	System	23 Sep 2020 09:20:24

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '22 Sep 2020 12:40'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 2'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:57:51', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ae8f4dca-3e8f-42a2-b315-3b258e65204e' User entered 'Yes (Y)'	System	24 Sep 2020 12:58:23
	System	24 Sep 2020 12:58:23

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:57:56', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ae8f4dca-3e8f-42a2-b315-3b258e65204e' User entered '97.0'	System	24 Sep 2020 12:58:23
	System	24 Sep 2020 12:58:23

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ae8f4dca-3e8f-42a2-b315-3b258e65204e' User entered 'No (N)'	System	24 Sep 2020 12:58:23
	System	24 Sep 2020 12:58:23

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:03', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ae8f4dca-3e8f-42a2-b315-3b258e65204e' User entered '24 Sep 2020 08:58'	System	24 Sep 2020 12:58:23
	System	24 Sep 2020 12:58:23

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 3'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:17', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '09eaaa01-f8fc-449f-9831-73b70ad88759'	System	25 Sep 2020 10:49:35
User entered 'Yes (Y)'	System	25 Sep 2020 10:49:35

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:22', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '09eaaa01-f8fc-449f-9831-73b70ad88759' User entered '98.1'	System	25 Sep 2020 10:49:35
	System	25 Sep 2020 10:49:35

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:29', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '09eaaa01-f8fc-449f-9831-73b70ad88759'	System	25 Sep 2020 10:49:35
User entered 'No (N)'	System	25 Sep 2020 10:49:35

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:32', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '09eaaa01-f8fc-449f-9831-73b70ad88759'	System	25 Sep 2020 10:49:35
User entered '25 Sep 2020 06:49'	System	25 Sep 2020 10:49:35

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 4'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:20', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6a1c0e11-fdf9-4a0c-a2a3-f6c19fcec8a3'	System	26 Sep 2020 12:45:36
User entered 'Yes (Y)'	System	26 Sep 2020 12:45:36

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:26', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6a1c0e11-fdf9-4a0c-a2a3-f6c19fcec8a3'	System	26 Sep 2020 12:45:36
User entered '98.0'	System	26 Sep 2020 12:45:36

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:30', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6a1c0e11-fdf9-4a0c-a2a3-f6c19fcec8a3'	System	26 Sep 2020 12:45:36
User entered 'No (N)'	System	26 Sep 2020 12:45:36

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:32', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6a1c0e11-fdf9-4a0c-a2a3-f6c19fcec8a3' User entered '26 Sep 2020 07:45'	System	26 Sep 2020 12:45:36
	System	26 Sep 2020 12:45:36

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 5'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 6'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:20', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '4c47f0f6-ec3e-45ad-9b8b-438c7e8c83c3' User entered 'Yes (Y)'	System	27 Sep 2020 17:17:33
	System	27 Sep 2020 17:17:33

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:25', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '4c47f0f6-ec3e-45ad-9b8b-438c7e8c83c3' User entered '97.2'	System	27 Sep 2020 17:17:33
	System	27 Sep 2020 17:17:33

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:27', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '4c47f0f6-ec3e-45ad-9b8b-438c7e8c83c3'	System	27 Sep 2020 17:17:33
User entered 'No (N)'	System	27 Sep 2020 17:17:33

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:30', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '4c47f0f6-ec3e-45ad-9b8b-438c7e8c83c3' User entered '27 Sep 2020 12:17'	System	27 Sep 2020 17:17:33
	System	27 Sep 2020 17:17:33

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 7'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:04:46', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '19317734-8079-441b-a6ea-a1d2f8cdc98e' User entered 'Yes (Y)'	System	29 Sep 2020 10:05:05
	System	29 Sep 2020 10:05:05

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:04:56', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '19317734-8079-441b-a6ea-a1d2f8cdc98e' User entered '99.0'	System	29 Sep 2020 10:05:05
	System	29 Sep 2020 10:05:05

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:04:59', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '19317734-8079-441b-a6ea-a1d2f8cdc98e' User entered 'No (N)'	System	29 Sep 2020 10:05:05
	System	29 Sep 2020 10:05:05

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:01', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '19317734-8079-441b-a6ea-a1d2f8cdc98e' User entered '29 Sep 2020 06:05'	System	29 Sep 2020 10:05:05
	System	29 Sep 2020 10:05:05

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:04', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2cff4ba3-7546-4418-8094-47f471524594'	System	22 Sep 2020 13:45:17
User entered 'None (1)'	System	22 Sep 2020 13:45:17

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:07', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2cff4ba3-7546-4418-8094-47f471524594'	System	22 Sep 2020 13:45:17
User entered 'No (N)'	System	22 Sep 2020 13:45:17

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:10', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2cff4ba3-7546-4418-8094-47f471524594' User entered 'No (N)'	System	22 Sep 2020 13:45:17
	System	22 Sep 2020 13:45:17

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:13', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2cff4ba3-7546-4418-8094-47f471524594'	System	22 Sep 2020 13:45:17
User entered 'None (1)'	System	22 Sep 2020 13:45:17

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:15', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2cff4ba3-7546-4418-8094-47f471524594' User entered '22 Sep 2020 09:45'	System	22 Sep 2020 13:45:17
	System	22 Sep 2020 13:45:17

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '22 Sep 2020 09:15'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '22 Sep 2020 11:45'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:20:30', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '14cffedb-92d9-4d62-974e-2fd5b108c235'	System	23 Sep 2020 09:20:51
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 09:20:51

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:20:36', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '14cffedb-92d9-4d62-974e-2fd5b108c235'	System	23 Sep 2020 09:20:51
User entered 'No (N)'	System	23 Sep 2020 09:20:51

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:20:41', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '14cffedb-92d9-4d62-974e-2fd5b108c235'	System	23 Sep 2020 09:20:51
User entered 'No (N)'	System	23 Sep 2020 09:20:51

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:20:45', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '14cffedb-92d9-4d62-974e-2fd5b108c235'	System	23 Sep 2020 09:20:51
User entered 'None (1)'	System	23 Sep 2020 09:20:51

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:20:48', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '14cffedb-92d9-4d62-974e-2fd5b108c235'	System	23 Sep 2020 09:20:51
User entered '23 Sep 2020 05:20'	System	23 Sep 2020 09:20:51

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '22 Sep 2020 12:40'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 2'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:12', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'dabaa5fa-eef1-492b-979a-b55840c24930'	System	24 Sep 2020 12:58:34
User entered 'None (1)'	System	24 Sep 2020 12:58:34

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:15', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'dabaa5fa-eef1-492b-979a-b55840c24930' User entered 'No (N)'	System	24 Sep 2020 12:58:34
	System	24 Sep 2020 12:58:34

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:18', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'dabaa5fa-eef1-492b-979a-b55840c24930' User entered 'No (N)'	System	24 Sep 2020 12:58:34
	System	24 Sep 2020 12:58:34

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:20', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'dabaa5fa-eef1-492b-979a-b55840c24930'	System	24 Sep 2020 12:58:34
User entered 'None (1)'	System	24 Sep 2020 12:58:34

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:22', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'dabaa5fa-eef1-492b-979a-b55840c24930' User entered '24 Sep 2020 08:58'	System	24 Sep 2020 12:58:34
	System	24 Sep 2020 12:58:34

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 3'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:36', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6e1df83c-c506-408f-859b-bcae94756daa'	System	25 Sep 2020 10:49:51
User entered 'None (1)'	System	25 Sep 2020 10:49:51

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:38', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6e1df83c-c506-408f-859b-bcae94756daa'	System	25 Sep 2020 10:49:51
User entered 'No (N)'	System	25 Sep 2020 10:49:51

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:41', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6e1df83c-c506-408f-859b-bcae94756daa'	System	25 Sep 2020 10:49:51
User entered 'No (N)'	System	25 Sep 2020 10:49:51

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:43', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6e1df83c-c506-408f-859b-bcae94756daa'	System	25 Sep 2020 10:49:51
User entered 'None (1)'	System	25 Sep 2020 10:49:51

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:46', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '6e1df83c-c506-408f-859b-bcae94756daa' User entered '25 Sep 2020 06:49'	System	25 Sep 2020 10:49:51
	System	25 Sep 2020 10:49:51

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 4'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:35', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'c0e7f2ae-7e11-42ab-bf80-da3bcb164a18'	System	26 Sep 2020 12:45:52
User entered 'None (1)'	System	26 Sep 2020 12:45:52

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:38', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'c0e7f2ae-7e11-42ab-bf80-da3bcb164a18'	System	26 Sep 2020 12:45:52
User entered 'No (N)'	System	26 Sep 2020 12:45:52

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:42', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'c0e7f2ae-7e11-42ab-bf80-da3bcb164a18'	System	26 Sep 2020 12:45:52
User entered 'No (N)'	System	26 Sep 2020 12:45:52

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:44', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'c0e7f2ae-7e11-42ab-bf80-da3bcb164a18'	System	26 Sep 2020 12:45:52
User entered 'None (1)'	System	26 Sep 2020 12:45:52

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:48', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'c0e7f2ae-7e11-42ab-bf80-da3bcb164a18' User entered '26 Sep 2020 07:45'	System	26 Sep 2020 12:45:52
	System	26 Sep 2020 12:45:52

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 5'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 6'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:35', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '64520bfa-91ed-4349-8d55-e0bb27311ca7'	System	27 Sep 2020 17:17:46
User entered 'None (1)'	System	27 Sep 2020 17:17:46

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:37', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '64520bfa-91ed-4349-8d55-e0bb27311ca7' User entered 'No (N)'	System	27 Sep 2020 17:17:46
	System	27 Sep 2020 17:17:46

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:39', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '64520bfa-91ed-4349-8d55-e0bb27311ca7'	System	27 Sep 2020 17:17:46
User entered 'No (N)'	System	27 Sep 2020 17:17:46

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:42', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '64520bfa-91ed-4349-8d55-e0bb27311ca7'	System	27 Sep 2020 17:17:46
User entered 'None (1)'	System	27 Sep 2020 17:17:46

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:44', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '64520bfa-91ed-4349-8d55-e0bb27311ca7' User entered '27 Sep 2020 12:17'	System	27 Sep 2020 17:17:46
	System	27 Sep 2020 17:17:46

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 7'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:05', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ad784db0-c4a6-4ac4-9459-69fe4c70f92e' User entered 'None (1)'	System	29 Sep 2020 10:05:17
	System	29 Sep 2020 10:05:17

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:07', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ad784db0-c4a6-4ac4-9459-69fe4c70f92e' User entered 'No (N)'	System	29 Sep 2020 10:05:17
	System	29 Sep 2020 10:05:17

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ad784db0-c4a6-4ac4-9459-69fe4c70f92e' User entered 'No (N)'	System	29 Sep 2020 10:05:17
	System	29 Sep 2020 10:05:17

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:12', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ad784db0-c4a6-4ac4-9459-69fe4c70f92e' User entered 'None (1)'	System	29 Sep 2020 10:05:17
	System	29 Sep 2020 10:05:17

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:15', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ad784db0-c4a6-4ac4-9459-69fe4c70f92e' User entered '29 Sep 2020 06:05'	System	29 Sep 2020 10:05:17
	System	29 Sep 2020 10:05:17

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:20', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8c61b4d7-51ae-41e8-8e2a-e9b2593a47bf' User entered 'None (0)'	System	22 Sep 2020 13:45:41
	System	22 Sep 2020 13:45:41

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:23', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8c61b4d7-51ae-41e8-8e2a-e9b2593a47bf' User entered 'None (0)'	System	22 Sep 2020 13:45:41
	System	22 Sep 2020 13:45:41

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:25', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8c61b4d7-51ae-41e8-8e2a-e9b2593a47bf' User entered 'None (0)'	System	22 Sep 2020 13:45:41
	System	22 Sep 2020 13:45:41

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:27', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8c61b4d7-51ae-41e8-8e2a-e9b2593a47bf' User entered 'None (0)'	System	22 Sep 2020 13:45:41
	System	22 Sep 2020 13:45:41

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:29', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8c61b4d7-51ae-41e8-8e2a-e9b2593a47bf' User entered 'None (0)'	System	22 Sep 2020 13:45:41
	System	22 Sep 2020 13:45:41

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:31', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8c61b4d7-51ae-41e8-8e2a-e9b2593a47bf' User entered 'None (0)'	System	22 Sep 2020 13:45:41
	System	22 Sep 2020 13:45:41

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:36', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8c61b4d7-51ae-41e8-8e2a-e9b2593a47bf' User entered 'No (N)'	System	22 Sep 2020 13:45:41
	System	22 Sep 2020 13:45:41

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-22T09:45:39', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8c61b4d7-51ae-41e8-8e2a-e9b2593a47bf' User entered '22 Sep 2020 09:45'	System	22 Sep 2020 13:45:41
	System	22 Sep 2020 13:45:41

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '22 Sep 2020 09:15'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '22 Sep 2020 11:45'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:20:54', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2607a7d1-572f-486f-a359-43a52b6b0deb' User entered 'None (0)'	System	23 Sep 2020 09:21:24
	System	23 Sep 2020 09:21:24

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:21:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2607a7d1-572f-486f-a359-43a52b6b0deb' User entered 'No interference with activity (1)'	System	23 Sep 2020 09:21:24
	System	23 Sep 2020 09:21:24

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:21:03', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2607a7d1-572f-486f-a359-43a52b6b0deb' User entered 'None (0)'	System	23 Sep 2020 09:21:24
	System	23 Sep 2020 09:21:24

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:21:06', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2607a7d1-572f-486f-a359-43a52b6b0deb' User entered 'None (0)'	System	23 Sep 2020 09:21:24
	System	23 Sep 2020 09:21:24

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:21:08', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2607a7d1-572f-486f-a359-43a52b6b0deb' User entered 'None (0)'	System	23 Sep 2020 09:21:24
	System	23 Sep 2020 09:21:24

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:21:13', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2607a7d1-572f-486f-a359-43a52b6b0deb' User entered 'No interference with activity (1)'	System	23 Sep 2020 09:21:24
	System	23 Sep 2020 09:21:24

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:21:18', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2607a7d1-572f-486f-a359-43a52b6b0deb' User entered 'No (N)'	System	23 Sep 2020 09:21:24
	System	23 Sep 2020 09:21:24

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-23T05:21:20', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '2607a7d1-572f-486f-a359-43a52b6b0deb' User entered '23 Sep 2020 05:21'	System	23 Sep 2020 09:21:24
	System	23 Sep 2020 09:21:24

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '22 Sep 2020 12:40'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 2'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:26', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '396ae1e6-4e5f-44ac-8c06-5d5c542628ac' User entered 'None (0)'	System	24 Sep 2020 12:58:48
	System	24 Sep 2020 12:58:48

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:31', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '396ae1e6-4e5f-44ac-8c06-5d5c542628ac'	System	24 Sep 2020 12:58:48
User entered 'No interference with activity (1)'	System	24 Sep 2020 12:58:48

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:33', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '396ae1e6-4e5f-44ac-8c06-5d5c542628ac' User entered 'None (0)'	System	24 Sep 2020 12:58:48
	System	24 Sep 2020 12:58:48

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:35', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '396ae1e6-4e5f-44ac-8c06-5d5c542628ac' User entered 'None (0)'	System	24 Sep 2020 12:58:48
	System	24 Sep 2020 12:58:48

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:37', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '396ae1e6-4e5f-44ac-8c06-5d5c542628ac' User entered 'None (0)'	System	24 Sep 2020 12:58:48
	System	24 Sep 2020 12:58:48

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:39', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '396ae1e6-4e5f-44ac-8c06-5d5c542628ac' User entered 'None (0)'	System	24 Sep 2020 12:58:48
	System	24 Sep 2020 12:58:48

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:41', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '396ae1e6-4e5f-44ac-8c06-5d5c542628ac' User entered 'No (N)'	System	24 Sep 2020 12:58:48
	System	24 Sep 2020 12:58:48

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-24T08:58:43', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '396ae1e6-4e5f-44ac-8c06-5d5c542628ac' User entered '24 Sep 2020 08:58'	System	24 Sep 2020 12:58:48
	System	24 Sep 2020 12:58:48

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 3'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:51', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a252bb6f-3550-4949-a1c8-25d282ea6dcd' User entered 'No interference with activity (1)'	System	25 Sep 2020 10:50:12
	System	25 Sep 2020 10:50:12

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:54', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a252bb6f-3550-4949-a1c8-25d282ea6dcd' User entered 'No interference with activity (1)'	System	25 Sep 2020 10:50:12
	System	25 Sep 2020 10:50:12

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:56', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a252bb6f-3550-4949-a1c8-25d282ea6dcd' User entered 'None (0)'	System	25 Sep 2020 10:50:12
	System	25 Sep 2020 10:50:12

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:49:58', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a252bb6f-3550-4949-a1c8-25d282ea6dcd' User entered 'None (0)'	System	25 Sep 2020 10:50:12
	System	25 Sep 2020 10:50:12

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:50:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a252bb6f-3550-4949-a1c8-25d282ea6dcd' User entered 'None (0)'	System	25 Sep 2020 10:50:12
	System	25 Sep 2020 10:50:12

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:50:02', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a252bb6f-3550-4949-a1c8-25d282ea6dcd' User entered 'None (0)'	System	25 Sep 2020 10:50:12
	System	25 Sep 2020 10:50:12

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:50:04', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a252bb6f-3550-4949-a1c8-25d282ea6dcd' User entered 'No (N)'	System	25 Sep 2020 10:50:12
	System	25 Sep 2020 10:50:12

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-25T06:50:06', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'a252bb6f-3550-4949-a1c8-25d282ea6dcd' User entered '25 Sep 2020 06:50'	System	25 Sep 2020 10:50:12
	System	25 Sep 2020 10:50:12

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 4'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:54', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '17513444-ad04-47a7-bfe6-78079f18c056' User entered 'None (0)'	System	26 Sep 2020 12:46:18
	System	26 Sep 2020 12:46:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:56', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '17513444-ad04-47a7-bfe6-78079f18c056' User entered 'None (0)'	System	26 Sep 2020 12:46:18
	System	26 Sep 2020 12:46:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:45:58', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '17513444-ad04-47a7-bfe6-78079f18c056'	System	26 Sep 2020 12:46:18
User entered 'None (0)'	System	26 Sep 2020 12:46:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:46:04', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '17513444-ad04-47a7-bfe6-78079f18c056' User entered 'None (0)'	System	26 Sep 2020 12:46:18
	System	26 Sep 2020 12:46:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:46:07', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '17513444-ad04-47a7-bfe6-78079f18c056' User entered 'None (0)'	System	26 Sep 2020 12:46:18
	System	26 Sep 2020 12:46:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:46:10', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '17513444-ad04-47a7-bfe6-78079f18c056' User entered 'None (0)'	System	26 Sep 2020 12:46:18
	System	26 Sep 2020 12:46:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:46:12', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '17513444-ad04-47a7-bfe6-78079f18c056' User entered 'No (N)'	System	26 Sep 2020 12:46:18
	System	26 Sep 2020 12:46:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-26T07:46:15', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '17513444-ad04-47a7-bfe6-78079f18c056' User entered '26 Sep 2020 07:46'	System	26 Sep 2020 12:46:18
	System	26 Sep 2020 12:46:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 5'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 6'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:47', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '425014e6-b8b9-4c09-adac-4a810776d57d' User entered 'None (0)'	System	27 Sep 2020 17:18:04
	System	27 Sep 2020 17:18:04

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:50', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '425014e6-b8b9-4c09-adac-4a810776d57d' User entered 'None (0)'	System	27 Sep 2020 17:18:04
	System	27 Sep 2020 17:18:04

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:52', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '425014e6-b8b9-4c09-adac-4a810776d57d' User entered 'None (0)'	System	27 Sep 2020 17:18:04
	System	27 Sep 2020 17:18:04

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:53', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '425014e6-b8b9-4c09-adac-4a810776d57d' User entered 'None (0)'	System	27 Sep 2020 17:18:04
	System	27 Sep 2020 17:18:04

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:55', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '425014e6-b8b9-4c09-adac-4a810776d57d' User entered 'None (0)'	System	27 Sep 2020 17:18:04
	System	27 Sep 2020 17:18:04

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:17:58', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '425014e6-b8b9-4c09-adac-4a810776d57d' User entered 'None (0)'	System	27 Sep 2020 17:18:04
	System	27 Sep 2020 17:18:04

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:18:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '425014e6-b8b9-4c09-adac-4a810776d57d' User entered 'No (N)'	System	27 Sep 2020 17:18:04
	System	27 Sep 2020 17:18:04

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-27T12:18:02', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '425014e6-b8b9-4c09-adac-4a810776d57d' User entered '27 Sep 2020 12:18'	System	27 Sep 2020 17:18:04
	System	27 Sep 2020 17:18:04

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	22 Sep 2020 13:43:18
User entered 'Day 7'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:18', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f905f055-6ca6-4a99-bf54-4d0f2e78df64'	System	29 Sep 2020 10:05:33
User entered 'None (0)'	System	29 Sep 2020 10:05:33

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:20', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f905f055-6ca6-4a99-bf54-4d0f2e78df64' User entered 'None (0)'	System	29 Sep 2020 10:05:33
	System	29 Sep 2020 10:05:33

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:21', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f905f055-6ca6-4a99-bf54-4d0f2e78df64'	System	29 Sep 2020 10:05:33
User entered 'None (0)'	System	29 Sep 2020 10:05:33

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:24', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f905f055-6ca6-4a99-bf54-4d0f2e78df64' User entered 'None (0)'	System	29 Sep 2020 10:05:33
	System	29 Sep 2020 10:05:33

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:25', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f905f055-6ca6-4a99-bf54-4d0f2e78df64'	System	29 Sep 2020 10:05:33
User entered 'None (0)'	System	29 Sep 2020 10:05:33

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:27', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f905f055-6ca6-4a99-bf54-4d0f2e78df64'	System	29 Sep 2020 10:05:33
User entered 'None (0)'	System	29 Sep 2020 10:05:33

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:29', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f905f055-6ca6-4a99-bf54-4d0f2e78df64'	System	29 Sep 2020 10:05:33
User entered 'No (N)'	System	29 Sep 2020 10:05:33

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-09-29T06:05:31', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'f905f055-6ca6-4a99-bf54-4d0f2e78df64'	System	29 Sep 2020 10:05:33
User entered '29 Sep 2020 06:05'	System	29 Sep 2020 10:05:33

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 13:43:18

US3222296

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 13:43:18

US3222296

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:13

US3222296

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '29 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:13

US3222296

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:13

US3222296

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered empty.	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:13

US3222296

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:20

US3222296

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User entered '1'	System	16 Oct 2020 18:22:20

US3222296

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:33

US3222296

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered '6 Oct 2020'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:33

US3222296

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:33

US3222296

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered empty.	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:33

US3222296

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:37

US3222296

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:35:55
User entered '1'	System	16 Oct 2020 18:22:37

US3222296

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:50

US3222296

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '14 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:50

US3222296

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:50

US3222296

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:22:50

US3222296

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 18:23:01

US3222296

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '1'	System	16 Oct 2020 18:23:01

US3222296

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	20 Oct 2020 14:02:17

US3222296

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '20 Oct 2020'	(b) (4) Alicia Cevera (b) (4)	20 Oct 2020 14:02:17
	(b) (4)	

US3222296

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Clinic (Clinic)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	20 Oct 2020 14:02:17

US3222296

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'VISIT3'	System	20 Oct 2020 14:02:17

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Alicia Cevera (b) (4)	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Alicia Cevera (b) (4)	20 Oct 2020 14:02:24
	(b) (4)	

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered empty.	System	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered empty.	System	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Alicia Cevera (b) (4)	20 Oct 2020 14:02:24
	(b) (4)	

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered empty.	System	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered empty.	System	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Alicia Cevera (b) (4)	20 Oct 2020 14:02:24
	(b) (4)	

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered empty.	System	20 Oct 2020 14:02:24

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11

US3222296

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:58

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11

US3222296

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	20 Oct 2020 14:02:30
	(b) (4)	

US3222296

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	20 Oct 2020 14:02:30

US3222296

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	20 Oct 2020 14:02:49

US3222296

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '20 Oct 2020'	(b) (4) Alicia Cevera (b) (4)	20 Oct 2020 14:02:49
	(b) (4)	

US3222296

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '09:15'	(b) (4) Alicia Cevera (b) (4) (b) (4)	20 Oct 2020 14:02:49

US3222296

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '20 Oct 2020 09:15'	System	20 Oct 2020 14:02:49

US3222296

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	20 Oct 2020 14:02:54

US3222296

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered '1'	System	20 Oct 2020 14:02:54

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 64'	System	23 Aug 2020 19:11:19

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-10-26T00:32:31', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'e057c906-61e9-4883-a079-17968c44b80e'	System	26 Oct 2020 04:32:45
User entered 'No (N)'	System	26 Oct 2020 04:32:45

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-10-26T00:32:38', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'e057c906-61e9-4883-a079-17968c44b80e'	System	26 Oct 2020 04:32:45
User entered 'No (N)'	System	26 Oct 2020 04:32:45

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-10-26T00:32:43', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'e057c906-61e9-4883-a079-17968c44b80e' User entered '26 Oct 2020 00:32:43'	System	26 Oct 2020 04:32:45
	System	26 Oct 2020 04:32:45

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered '23 Oct 2020 00:01'	System	23 Aug 2020 19:11:19

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered '27 Oct 2020 23:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 71'	System	23 Aug 2020 19:11:19

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-01T09:32:11', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'dad65e37-5f7e-49bb-bb04-2ab462d48db2'	System	01 Nov 2020 14:32:24
User entered 'No (N)'	System	01 Nov 2020 14:32:24

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-01T09:32:18', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'dad65e37-5f7e-49bb-bb04-2ab462d48db2'	System	01 Nov 2020 14:32:24
User entered 'No (N)'	System	01 Nov 2020 14:32:24

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-01T09:32:22', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'dad65e37-5f7e-49bb-bb04-2ab462d48db2' User entered '01 Nov 2020 09:32:22'	System	01 Nov 2020 14:32:24
	System	01 Nov 2020 14:32:24

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered '30 Oct 2020 00:01'	System	23 Aug 2020 19:11:19

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered '03 Nov 2020 23:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 78'	System	23 Aug 2020 19:11:19

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:52:38', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered 'Yes (Y)'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:52:43', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered 'No (N)'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:52:54', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered 'Yes (Y)'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '1'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '1'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '1'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '0'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:21', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0'	System	09 Nov 2020 02:53:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:27', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered 'Yes (Y)'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:32', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0'	System	09 Nov 2020 02:53:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-08T21:53:38', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '11329c78-0300-410b-8e58-4bbe8413fde0' User entered '08 Nov 2020 21:53:38'	System	09 Nov 2020 02:53:48
	System	09 Nov 2020 02:53:48

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered '06 Nov 2020 00:01'	System	23 Aug 2020 19:11:19

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:12:44
Data entry locked.	System	23 Aug 2020 19:11:19
User entered '10 Nov 2020 23:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33
Data entry locked.	System	23 Aug 2020 19:11:19
User entered 'Day 92'	System	23 Aug 2020 19:11:19

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

US3222296

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

US3222296

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

US3222296

Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

US3222296

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

US3222296

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33
Data entry locked.	System	23 Aug 2020 19:11:19
User entered '20 Nov 2020 00:01'	System	23 Aug 2020 19:11:19

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:57
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	09 Apr 2021 16:10:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:28:33
Data entry locked.	System	23 Aug 2020 19:11:19
User entered '24 Nov 2020 23:59'	System	23 Aug 2020 19:11:19

US3222296

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:28:33

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '17 Nov 2020 00:01'	System	20 Nov 2020 01:28:33

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '21 Nov 2020 23:59'	System	20 Nov 2020 01:28:33

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-24T06:04:15', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '9dc7464e-810f-4e05-b4af-d7fb6205ab35'	System	24 Nov 2020 11:04:32
User entered 'No (N)'	System	24 Nov 2020 11:04:32

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-24T06:04:21', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '9dc7464e-810f-4e05-b4af-d7fb6205ab35'	System	24 Nov 2020 11:04:32
User entered 'No (N)'	System	24 Nov 2020 11:04:32

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1FF46925-EE44-424E-9EB4-4883857FF5D3)', Time: '2020-11-24T06:04:30', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '9dc7464e-810f-4e05-b4af-d7fb6205ab35'	System	24 Nov 2020 11:04:32
User entered '24 Nov 2020 06:04:30'	System	24 Nov 2020 11:04:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '24 Nov 2020 00:01'	System	20 Nov 2020 01:28:33

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '28 Nov 2020 23:59'	System	20 Nov 2020 01:28:33

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:28:33

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '01 Dec 2020 00:01'	System	20 Nov 2020 01:28:33

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '05 Dec 2020 23:59'	System	20 Nov 2020 01:28:33

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '08 Dec 2020 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '12 Dec 2020 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:07:07
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'updated and AE added' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:31:35
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 06:07:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-15T10:57:58', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '5719c8d3-872b-406c-94eb-52225d61b206'	System	15 Dec 2020 15:58:43
User entered 'Yes (Y)'	System	15 Dec 2020 15:58:43

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-15T10:58:04', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '5719c8d3-872b-406c-94eb-52225d61b206'	System	15 Dec 2020 15:58:43
User entered 'No (N)'	System	15 Dec 2020 15:58:43

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-15T10:58:11', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '5719c8d3-872b-406c-94eb-52225d61b206'	System	15 Dec 2020 15:58:43
User entered 'No (N)'	System	15 Dec 2020 15:58:43

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-15T10:58:21', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '5719c8d3-872b-406c-94eb-52225d61b206'	System	15 Dec 2020 15:58:43
User entered 'Yes (Y)'	System	15 Dec 2020 15:58:43

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-15T10:58:28', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '5719c8d3-872b-406c-94eb-52225d61b206'	System	15 Dec 2020 15:58:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Dec 2020 15:58:43

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-15T10:58:32', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '5719c8d3-872b-406c-94eb-52225d61b206'	System	15 Dec 2020 15:58:43
User entered '15 Dec 2020 10:58:32'	System	15 Dec 2020 15:58:43

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '15 Dec 2020 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '19 Dec 2020 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-24T16:40:51', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3fda003c-3302-4931-be04-e7e06e7a532f'	System	24 Dec 2020 21:41:20
User entered 'No (N)'	System	24 Dec 2020 21:41:20

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-24T16:41:09', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3fda003c-3302-4931-be04-e7e06e7a532f'	System	24 Dec 2020 21:41:20
User entered 'No (N)'	System	24 Dec 2020 21:41:20

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-24T16:41:18', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3fda003c-3302-4931-be04-e7e06e7a532f' User entered '24 Dec 2020 16:41:18'	System	24 Dec 2020 21:41:20
	System	24 Dec 2020 21:41:20

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '22 Dec 2020 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '26 Dec 2020 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-29T03:50:43', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '123f9482-5b68-42cb-8ad0-b0daae68a7db'	System	29 Dec 2020 08:50:55
User entered 'No (N)'	System	29 Dec 2020 08:50:55

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-29T03:50:49', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '123f9482-5b68-42cb-8ad0-b0daae68a7db' User entered 'No (N)'	System	29 Dec 2020 08:50:55
	System	29 Dec 2020 08:50:55

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2020-12-29T03:50:53', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '123f9482-5b68-42cb-8ad0-b0daae68a7db' User entered '29 Dec 2020 03:50:53'	System	29 Dec 2020 08:50:55
	System	29 Dec 2020 08:50:55

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '29 Dec 2020 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '02 Jan 2021 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-05T19:13:45', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '4dbfb247-059b-4e6d-ad8f-75c2aa62cdd1'	System	06 Jan 2021 00:13:56
User entered 'No (N)'	System	06 Jan 2021 00:13:56

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-05T19:13:49', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '4dbfb247-059b-4e6d-ad8f-75c2aa62cdd1'	System	06 Jan 2021 00:13:56
User entered 'No (N)'	System	06 Jan 2021 00:13:56

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-05T19:13:53', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '4dbfb247-059b-4e6d-ad8f-75c2aa62cdd1'	System	06 Jan 2021 00:13:56
User entered '05 Jan 2021 19:13:53'	System	06 Jan 2021 00:13:56

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '05 Jan 2021 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '09 Jan 2021 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-13T12:02:44', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3a34f074-6e32-4f40-843e-1cb76a307791' User entered 'No (N)'	System	13 Jan 2021 17:03:18
	System	13 Jan 2021 17:03:18

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-13T12:02:48', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3a34f074-6e32-4f40-843e-1cb76a307791'	System	13 Jan 2021 17:03:18
User entered 'No (N)'	System	13 Jan 2021 17:03:18

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-13T12:02:51', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3a34f074-6e32-4f40-843e-1cb76a307791' User entered '13 Jan 2021 12:02:51'	System	13 Jan 2021 17:03:18
	System	13 Jan 2021 17:03:18

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '12 Jan 2021 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '16 Jan 2021 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-19T19:49:51', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3821d4cf-ca2b-48fc-ac35-f5f59ac035b0'	System	20 Jan 2021 00:50:07
User entered 'No (N)'	System	20 Jan 2021 00:50:07

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-19T19:49:55', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3821d4cf-ca2b-48fc-ac35-f5f59ac035b0'	System	20 Jan 2021 00:50:07
User entered 'No (N)'	System	20 Jan 2021 00:50:07

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-19T19:49:59', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3821d4cf-ca2b-48fc-ac35-f5f59ac035b0' User entered '19 Jan 2021 19:49:59'	System	20 Jan 2021 00:50:07
	System	20 Jan 2021 00:50:07

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '19 Jan 2021 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '23 Jan 2021 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-28T07:05:50', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'b97326f2-2414-49e9-ac5e-c614a265cc45'	System	28 Jan 2021 12:07:06
User entered 'Yes (Y)'	System	28 Jan 2021 12:07:06

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-28T07:05:55', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'b97326f2-2414-49e9-ac5e-c614a265cc45'	System	28 Jan 2021 12:07:06
User entered 'No (N)'	System	28 Jan 2021 12:07:06

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-28T07:06:01', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'b97326f2-2414-49e9-ac5e-c614a265cc45'	System	28 Jan 2021 12:07:06
User entered 'No (N)'	System	28 Jan 2021 12:07:06

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-28T07:06:43', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'b97326f2-2414-49e9-ac5e-c614a265cc45'	System	28 Jan 2021 12:07:06
User entered 'Yes (Y)'	System	28 Jan 2021 12:07:06

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-28T07:06:52', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'b97326f2-2414-49e9-ac5e-c614a265cc45'	System	28 Jan 2021 12:07:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Jan 2021 12:07:06

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-01-28T07:06:56', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'b97326f2-2414-49e9-ac5e-c614a265cc45'	System	28 Jan 2021 12:07:06
User entered '28 Jan 2021 07:06:56'	System	28 Jan 2021 12:07:06

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '26 Jan 2021 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '30 Jan 2021 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-02T00:03:20', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '054efd2c-eba3-4982-ad9d-5d499578f207'	System	02 Feb 2021 05:03:51
User entered 'Yes (Y)'	System	02 Feb 2021 05:03:51

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-02T00:03:23', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '054efd2c-eba3-4982-ad9d-5d499578f207'	System	02 Feb 2021 05:03:51
User entered 'No (N)'	System	02 Feb 2021 05:03:51

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-02T00:03:28', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '054efd2c-eba3-4982-ad9d-5d499578f207'	System	02 Feb 2021 05:03:51
User entered 'No (N)'	System	02 Feb 2021 05:03:51

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-02T00:03:33', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '054efd2c-eba3-4982-ad9d-5d499578f207'	System	02 Feb 2021 05:03:51
User entered 'Yes (Y)'	System	02 Feb 2021 05:03:51

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-02T00:03:37', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '054efd2c-eba3-4982-ad9d-5d499578f207'	System	02 Feb 2021 05:03:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Feb 2021 05:03:51

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-02T00:03:40', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '054efd2c-eba3-4982-ad9d-5d499578f207'	System	02 Feb 2021 05:03:51
User entered '02 Feb 2021 00:03:40'	System	02 Feb 2021 05:03:51

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '02 Feb 2021 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '06 Feb 2021 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-09T04:12:56', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '31ebdb65-5894-4797-9e12-dba63eb331eb' User entered 'No (N)'	System	09 Feb 2021 09:13:06
	System	09 Feb 2021 09:13:06

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-09T04:13:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '31ebdb65-5894-4797-9e12-dba63eb331eb' User entered 'No (N)'	System	09 Feb 2021 09:13:06
	System	09 Feb 2021 09:13:06

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-09T04:13:03', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '31ebdb65-5894-4797-9e12-dba63eb331eb' User entered '09 Feb 2021 04:13:03'	System	09 Feb 2021 09:13:06
	System	09 Feb 2021 09:13:06

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '09 Feb 2021 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '13 Feb 2021 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-18T12:00:53', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'dfece666-e28c-436b-98b4-69e94d4264df' User entered 'No (N)'	System	18 Feb 2021 17:03:39
	System	18 Feb 2021 17:03:39

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-18T12:00:57', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'dfece666-e28c-436b-98b4-69e94d4264df' User entered 'No (N)'	System	18 Feb 2021 17:03:39
	System	18 Feb 2021 17:03:39

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-18T12:01:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'dfece666-e28c-436b-98b4-69e94d4264df' User entered '18 Feb 2021 12:01:00'	System	18 Feb 2021 17:03:39
	System	18 Feb 2021 17:03:39

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '16 Feb 2021 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '20 Feb 2021 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-23T07:54:54-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ddd7acf1-6099-47e7-8170-bce4cc066487'	System	23 Feb 2021 12:55:26
User entered 'Yes (Y)'	System	23 Feb 2021 12:55:26

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-23T07:54:58-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ddd7acf1-6099-47e7-8170-bce4cc066487'	System	23 Feb 2021 12:55:26
User entered 'No (N)'	System	23 Feb 2021 12:55:26

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-23T07:55:02-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ddd7acf1-6099-47e7-8170-bce4cc066487'	System	23 Feb 2021 12:55:26
User entered 'No (N)'	System	23 Feb 2021 12:55:26

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-23T07:55:11-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ddd7acf1-6099-47e7-8170-bce4cc066487'	System	23 Feb 2021 12:55:26
User entered 'Yes (Y)'	System	23 Feb 2021 12:55:26

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-23T07:55:14-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ddd7acf1-6099-47e7-8170-bce4cc066487'	System	23 Feb 2021 12:55:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Feb 2021 12:55:26

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-02-23T07:55:16-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: 'ddd7acf1-6099-47e7-8170-bce4cc066487'	System	23 Feb 2021 12:55:26
User entered '23 Feb 2021 12:55:16'	System	23 Feb 2021 12:55:26

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '23 Feb 2021 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '27 Feb 2021 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-03-02T08:20:44-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '93744142-b3cd-4234-8ecb-14d2e405a811'	System	02 Mar 2021 13:20:56
User entered 'No (N)'	System	02 Mar 2021 13:20:56

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-03-02T08:20:49-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '93744142-b3cd-4234-8ecb-14d2e405a811'	System	02 Mar 2021 13:20:56
User entered 'No (N)'	System	02 Mar 2021 13:20:56

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-03-02T08:20:54-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '93744142-b3cd-4234-8ecb-14d2e405a811'	System	02 Mar 2021 13:20:56
User entered '02 Mar 2021 08:20:54'	System	02 Mar 2021 13:20:56

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '02 Mar 2021 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '06 Mar 2021 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-03-09T05:19:20-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3ba00785-3d9a-41dd-8053-0b6d1d0bb21e'	System	09 Mar 2021 10:19:35
User entered 'No (N)'	System	09 Mar 2021 10:19:35

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-03-09T05:19:26-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3ba00785-3d9a-41dd-8053-0b6d1d0bb21e'	System	09 Mar 2021 10:19:35
User entered 'No (N)'	System	09 Mar 2021 10:19:35

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-03-09T05:19:30-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '3ba00785-3d9a-41dd-8053-0b6d1d0bb21e'	System	09 Mar 2021 10:19:35
User entered '09 Mar 2021 05:19:30'	System	09 Mar 2021 10:19:35

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '09 Mar 2021 00:01'	System	20 Nov 2020 01:28:33

US3222296

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:28:33
Amendment Manager: User entered '13 Mar 2021 23:59'	System	20 Nov 2020 01:28:33

US3222296

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:05:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-03-02T08:20:59-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8df25f7f-aba9-4816-854a-04968864fa7d'	System	02 Mar 2021 13:21:06
User entered 'No (N)'	System	02 Mar 2021 13:21:06

US3222296

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:05:58

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (04D4DB50-4D60-4FF2-ADE0-4EA134753682)', Time: '2021-03-02T08:21:02-05:00', User OID: 'PatientReportedOutcome (US3222296)', ODM File OID: '8df25f7f-aba9-4816-854a-04968864fa7d'	System	02 Mar 2021 13:21:06
User entered '02 Mar 2021 08:21:02'	System	02 Mar 2021 13:21:06

US3222296

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:01:50

US3222296

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '15 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:01:50

US3222296

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:01:50

US3222296

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:01:50

US3222296

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	01 Dec 2020 14:00:03

US3222296

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:36:11
User entered 'I'	System	01 Dec 2020 14:00:03

US3222296

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:30
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	heather jackson (b) (4)	21 Dec 2020 19:02:33

US3222296

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:30
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '08 Dec 2020'	heather jackson (b) (4)	21 Dec 2020 19:02:33

US3222296

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:30
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	21 Dec 2020 19:02:33

US3222296

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:30
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	heather jackson (b) (4)	21 Dec 2020 19:02:33

US3222296

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:30
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	heather jackson (b) (4)	21 Dec 2020 19:02:36

US3222296

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:30
User entered 'I'	System	21 Dec 2020 19:02:36

US3222296

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:14
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:23:35

US3222296

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:14
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:23:35

US3222296

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:14
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:23:35

US3222296

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:14
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Tried 3 attempts at different times and left Voicemail with no callback or answer.'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:23:35

US3222296

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:14
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:23:42

US3222296

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:14
User entered '1'	System	21 Jan 2021 15:23:42

US3222296

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	01 Apr 2021 02:55:51

US3222296

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered empty.	douglas winter (b) (4) (b) (4)	01 Apr 2021 02:55:51

US3222296

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered empty.	douglas winter (b) (4) (b) (4)	01 Apr 2021 02:55:51

US3222296

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered empty.	douglas winter (b) (4) (b) (4)	01 Apr 2021 02:55:51

US3222296

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:10:56
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	01 Apr 2021 02:55:58

US3222296

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:10:56
User entered '1'	System	01 Apr 2021 02:55:58

US3222296

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:10:45

US3222296

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered empty.	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:10:45

US3222296

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered empty.	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:10:45

US3222296

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	09 Apr 2021 16:10:45

US3222296

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:38:13

US3222296

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '12 Feb 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:38:13

US3222296

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[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 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Clinic (Clinic)'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:38:13

US3222296

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User entered 'UNBLND_DECIDE'	System	12 Feb 2021 21:38:13

US3222296

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:58

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '12 Feb 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:38:52

US3222296

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:58

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:25:53

US3222296

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:58

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Feb 2021 21:39:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Feb 2021 21:39:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Toney (b) (4)	12 Feb 2021 21:39:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Feb 2021 21:38:52
User entered empty.	System	12 Feb 2021 21:38:52
	Diana Toney (b) (4)	12 Feb 2021 21:38:52
	(b) (4)	

US3222296

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:58

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:25:53

US3222296

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:58

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '12 Feb 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:38:52

US3222296

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:58

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:38:52

US3222296

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:58

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:38:52

US3222296

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:58

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:38:52

US3222296

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:58

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:38:52

US3222296

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:58

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User entered empty.	System	12 Feb 2021 21:38:52

US3222296

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:58

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User entered empty.	System	12 Feb 2021 21:38:52

US3222296

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:39:28

US3222296

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '12 Feb 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:39:28

US3222296

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '11:20'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:39:28

US3222296

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User entered '12 Feb 2021 11:20'	System	12 Feb 2021 21:39:28

US3222296

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:39:52

US3222296

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '12 Feb 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:39:52

US3222296

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '11:23'	(b) (4) Diana Toney (b) (4) (b) (4)	12 Feb 2021 21:39:52

US3222296

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:35:25
User entered '12 Feb 2021 11:23'	System	12 Feb 2021 21:39:52

US3222296

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:03:45
User closed query 'SAE hospital records from 04Feb2021 discharge indicate subject had a thymectomy on 04Dec2020. Please determine why and enter an AE for diagnosis. Please record this new AE in the source and in this CRF.' (Site from CRA). User closed query 'Per CDM: Per previous query regarding Day 187 on Safety Follow-up Diary, response is "UPDATED"; however, the correction/update is not obvious please provide location of update such as the form/log line number/data field corrected/updated. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 21:43:26
Query 'Per CDM: Per previous query regarding Day 187 on Safety Follow-up Diary, response is "UPDATED"; however, the correction/update is not obvious please provide location of update such as the form/log line number/data field corrected/updated. Thank you. ' answered with 'CORRECTED DROP DATE TO 12/FEB/2021 THIS IS AFTER DROP FROM STUDY.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 11:52:42
Query 'Per CDM: Per previous query regarding Day 187 on Safety Follow-up Diary, response is "UPDATED"; however, the correction/update is not obvious please provide location of update such as the form/log line number/data field corrected/updated. Thank you. ' answered with 'CORRECTED DROP DATE TO 12/FEB/2021 THIS IS AFTER DROP FROM STUDY.' (Site from DM).	douglas winter (b) (4) (b) (4)	12 Apr 2021 15:02:29
User opened query 'Per CDM: Per previous query regarding Day 187 on Safety Follow-up Diary, response is "UPDATED"; however, the correction/update is not obvious please provide location of update such as the form/log line number/data field corrected/updated. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:10:41
User closed query 'Per DM CLR: Per Day 187 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:09:27

US3222296

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Day 187 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:46:50
Query 'SAE hospital records from 04Feb2021 discharge indicate subject had a thymectomy on 04Dec2020. Please determine why and enter an AE for diagnosis. Please record this new AE in the source and in this CRF.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:46:39
User opened query 'Per DM CLR: Per Day 187 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 04:08:32
User opened query 'SAE hospital records from 04Feb2021 discharge indicate subject had a thymectomy on 04Dec2020. Please determine why and enter an AE for diagnosis. Please record this new AE in the source and in this CRF.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:15:29
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:12
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	20 Oct 2020 17:01:49
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	10 Oct 2020 00:10:01

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:20:24
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'PNEUMONIA IS NOT A COVID SYMPTOM' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Nov 2020 15:54:04
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 21:06:09
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 17:12:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 17:12:36
Data point term sent to Coder System	System	20 Oct 2020 17:12:17
User entered 'Pneumonia'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Oct 2020 17:11:58
User entered '00:00' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:58
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Oct 2020 17:11:38
User entered empty.	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 00:00'	System	20 Oct 2020 17:11:58
User entered empty.	System	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 07:10:51
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:37:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:36:32
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 07:21:52
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Apr 2021 15:36:53
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	05 Apr 2021 15:36:53
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Apr 2021 15:36:32
User entered '20 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:36:32
User entered empty.	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:37:12
User entered '23:59' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:37:12
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:36:32
User entered empty.	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered '20 Oct 2020 23:59'	System	05 Apr 2021 15:37:12
User entered empty.	System	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

Number of Days in ICU

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

None

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:52:35
User entered '0'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:36:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Previous response noted,however on ConProc eCRF the CT scan date has been recorded as 04Oct2020 which does not match with the date 23Sep2020 as mentioned in the SAE narrative. Please review and confirm the data else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 11:02:56
Query 'Per DM CLR: Previous response noted,however on ConProc eCRF the CT scan date has been recorded as 04Oct2020 which does not match with the date 23Sep2020 as mentioned in the SAE narrative. Please review and confirm the data else clarify.' answered with 'TRANSCRIPTION ERROR.' (Site from DM).	douglas winter (b) (4) (b) (4)	09 Apr 2021 15:46:30
User entered 'ON 04/OCT/2020 PATIENT HAD A CT SCAN WHICH CONFIRMED DOUBLE PNEUMONIA. THE CT ALSO SHOWED A MASS ON HER LUNG WHICH SHE WILL HAVE A BIOPSY AND SHE WILL THEN CONTACT THE SITE WITH THEIR FINDINGS.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Apr 2021 15:46:26
User opened query 'Per DM CLR: Previous response noted,however on ConProc eCRF the CT scan date has been recorded as 04Oct2020 which does not match with the date 23Sep2020 as mentioned in the SAE narrative. Please review and confirm the data else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 07:13:55
User closed query 'Per DM CLR: SAE Narrative = PATIENT HAD A CT SCAN WHICH CONFIRMED DOUBLE PNEUMONIA. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 07:13:55
Query 'Per DM CLR: SAE Narrative = PATIENT HAD A CT SCAN WHICH CONFIRMED DOUBLE PNEUMONIA. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:37:25

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = PATIENT HAD A CT SCAN WHICH CONFIRMED DOUBLE PNEUMONIA. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 00:24:38
User entered 'On 23/Sep/2020 patient had a CT scan which confirmed double pneumonia. The CT also showed a mass on her lung which she will have a biopsy and she will then contact the site with their findings.'	douglas winter (b) (4)	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:58

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:11:38

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:41:42
User entered 'USA-US104-2021-mRNA-1273-P301000008'	System	09 Feb 2021 13:41:30
User entered 'New'	(b) (4), (b) (6)	09 Feb 2021 13:41:30

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: If subject has a history of invasive thymoma, please update eCRF accordingly. ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:15:20
User opened query 'PV Query: If subject has a history of invasive thymoma, please update eCRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 12:40:57
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:43:41
User closed query 'PV Query: Please consider reporting the procedure complication (spleen nicked) as an SAE as it required the subject to be placed in ICU and possibly extended her hospitalization.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 16:46:16
User closed query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 12:43:22
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Mediastinal neoplasms malignant, PT: Thymoma malignant, LLT: Thymoma malignant invasive - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 15:45:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 15:45:45
User closed query 'For coding purposes, For coding purposes, ROBOTIC DIAPHRAGM PLICATION is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	System	05 Apr 2021 15:32:37
Query 'For coding purposes, For coding purposes, ROBOTIC DIAPHRAGM PLICATION is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'corrected' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 15:32:37

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:32:28
Query 'PV Query: Please consider reporting the procedure complication (spleen nicked) as an SAE as it required the subject to be placed in ICU and possibly extended her hospitalization.' answered with 'updated per hospital records' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:32:20
Data point term sent to Coder DataPoint Un-verified.	System (b) (4), (b) (6)	05 Apr 2021 15:32:10 05 Apr 2021 15:32:05
User entered 'Invasive thymoma' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:32:05
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:39
User opened query 'For coding purposes, For coding purposes, ROBOTIC DIAPHRAGM PLICATION is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	Coder Import (b) (4) (b) (4)	10 Mar 2021 12:16:50
User opened query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 02:12:35
User opened query 'PV Query: Please consider reporting the procedure complication (spleen nicked) as an SAE as it required the subject to be placed in ICU and possibly extended her hospitalization.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 14:37:10
Data point term sent to Coder	System	08 Feb 2021 17:19:47
User entered 'Robotic Diaphragm plication'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:42
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:44
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:46
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:48
User entered '14 Jan 2021'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:50
User entered empty.	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:51
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

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.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:15:28
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)	28 Apr 2021 12:36:45
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:02:50
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)	16 Apr 2021 09:43:31
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:54
User entered '21 Jan 2021'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:56
User entered empty.	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:42:59
User entered 'Grade 3/Severe (Grade 3/Severe)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:01
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	08 Feb 2021 17:19:16
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	08 Feb 2021 17:18:53
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:27
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:12
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:28
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:14
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:30
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:16
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	08 Feb 2021 17:19:16
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	08 Feb 2021 17:19:16
User entered '1' reason for change: Data Entry Error	Diana Toney (b) (4)	08 Feb 2021 17:19:16
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	08 Feb 2021 17:18:53
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:18:10
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 12:36:30
User closed query 'Please file hospital records in subject chart.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 15:44:00
Query 'Please file hospital records in subject chart.' answered with 'pending hospital records' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 15:33:02
User opened query 'Please file hospital records in subject chart.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:04:36
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 17:04:13
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:04:10
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:33
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:18
User entered '14 Jan 2021'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 12:17:57
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:18:16
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 12:37:14
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:20:59
User entered '31 Jan 2021' reason for change: Data Entry Error	douglas winter (b) (4)	23 Apr 2021 20:18:03
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'RECORDS WERE SENT 21/FEB/2021' (Site from Safety).	douglas winter (b) (4)	23 Apr 2021 19:44:21
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:47:34

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' canceled (Site from Safety). User opened query '	(b) (4), (b) (6)	16 Apr 2021 09:47:14
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	(b) (4), (b) (6)	16 Apr 2021 09:44:38
PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).		
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:35
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:19
User entered '21 Jan 2021'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:21
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User closed query 'Participant was not hospitalized or System Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	08 Feb 2021 17:19:16
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	08 Feb 2021 17:19:16
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	08 Feb 2021 17:18:53
User entered '4'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:40
User entered 'Not Related (NOT RELATED)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:43:44
User entered 'Not Related (NOT RELATED)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'PV Query: As subject received both scheduled doses of study drug, please update action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 12:17:35
Query 'PV Query: As the last dose of mRNA-1273 was given on 22 Sep 2020 please update the action taken with mRNA-1273 from none to not applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:18:29
DataPoint Un-verified.	Diana Toney (b) (4)	28 Apr 2021 12:40:41
User entered 'None (NONE)' reason for change: Data Entry Error	Diana Toney (b) (4)	28 Apr 2021 12:40:41
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 22 Sep 2020 please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 12:36:06
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:48:04
User closed query 'PV Query: As subject received both scheduled doses of study drug, please update action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:03:00
Query 'PV Query: As subject received both scheduled doses of study drug, please update action taken from none to not applicable.' answered with 'updated' (Site from Safety).	Amber Vasquez (b) (4)	16 Apr 2021 17:13:01
DataPoint Un-verified.	Amber Vasquez (b) (4)	16 Apr 2021 17:12:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amber Vasquez (b) (4)	16 Apr 2021 17:12:53
User opened query 'PV Query: As subject received both scheduled doses of study drug, please update action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:05:01
User closed query 'Source indicates this is "None". Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:31:24
Query 'Source indicates this is "None". Please confirm and revise if necessary.' answered with 'updated, not related to IP' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 15:33:16

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:32:05
User opened query 'Source indicates this is "None". Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 16:44:55
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 17:22:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 17:22:59
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:22:59
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 17:18:53
User entered empty.	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:49:24
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:18:41
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 12:37:42
User closed query 'Per CDM: ConMed Check box is updated however corresponding ConMed page is not updated. Please review and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 11:04:39
Query 'Per CDM: ConMed Check box is updated however corresponding ConMed page is not updated. Please review and update accordingly, else clarify. ' answered with 'awaiting hospital dc records. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:34:25
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:49:07
User opened query 'Per CDM: ConMed Check box is updated however corresponding ConMed page is not updated. Please review and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 17:30:39
User entered 'I'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:49:09
User entered '1'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Outcome](#)

Audit	User	Time (GMT)
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.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:18:46
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)	28 Apr 2021 12:37:30
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.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:02:45
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)	16 Apr 2021 09:45:17
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:49:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:49:21
User entered empty.	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please resend a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 12:18:07
User opened query 'PV Query: Another SAE event of invasive thymoma was reported in Dec. Please confirm if these were 2 separate events. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 12:17:47
User opened query 'PV Query: As per the concomitant section of CRF, the subject was started on oxycodone for invasive thymoma on 31 Jan 2021. But the event stop date reported is 21 Jan 2021. Please reconcile the event stop date according to the treatment given, or please state the reason to start treatment after the event recovered. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 12:17:24
Query 'IQVIA Medical request: Please clarify reason for recent surgery that caused hematoma of spleen as noted in the source document narrative.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:18:55
User opened query 'IQVIA Medical request: Please clarify reason for recent surgery that caused hematoma of spleen as noted in the source document narrative.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 12:41:13
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:47:26
User closed query 'PV Query: As per the concomitant section of CRF, the subject was started on oxycodone for invasive thymoma on 31 Jan 2021. But the event stop date reported is 21 Jan 2021. Please reconcile the event stop date according to the treatment given, or please state the reason to start treatment after the event recovered. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:21:36
User closed query 'IQVIA Medical request: Please clarify reason for recent surgery that caused hematoma of spleen as noted in the source document narrative.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:21:32

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:21:21
User closed query 'PV Query: If subject has a history of invasive thymoma, please update eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:21:13
Query 'PV Query: If subject has a history of invasive thymoma, please update eCRF accordingly.' answered with 'AE WAS ADDED FOR INVASIVE THYMOMA WHAT ELSE DO I NEED TO DO?' (Site from Safety).	douglas winter (b) (4) (b) (4)	23 Apr 2021 20:20:03
Query 'PV Query: As per the concomitant section of CRF, the subject was started on oxycodone for invasive thymoma on 31 Jan 2021. But the event stop date reported is 21 Jan 2021. Please reconcile the event stop date according to the treatment given, or please state the reason to start treatment after the event recovered. ' answered with 'CORRECTED DATE' (Site from Safety).	douglas winter (b) (4) (b) (4)	23 Apr 2021 20:18:15
Query 'IQVIA Medical request: Please clarify reason for recent surgery that caused hematoma of spleen as noted in the source document narrative.' answered with 'ADDED ADDITIONAL INFO IN NARRATIVE' (Site from Safety).	douglas winter (b) (4) (b) (4)	23 Apr 2021 20:16:21
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	23 Apr 2021 20:16:15
User entered 'SUBJECT HAD PROCEDURE TO HAVE ROBOTIC DIAPHRAGM PPLICATION AND THE PROCEDURE KNICKED HER SPLEEN WHICH CAUSED HER TO HAVE A HEMATOMA OF HER SPLEEN AND CAUSED HER TO BE PLACED IN ICU FOR 4 OUT OF THE 8. SARS COV2 COVID-19 PCR NEGATIVE. SHE WAS HOSPITALIZED. MEDICAL RECORDS REQUEST WAS SENT.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Apr 2021 20:16:15

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'SARS COV2 COVID-19 PCR NEGATIVE' (Site from Safety).	douglas winter (b) (4) (b) (4)	23 Apr 2021 20:00:34
Query 'PV Re-Query: Please provide the treatment medication given for the event. If none, please state so. Please leave open until receipt of hospital records.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:03:31
User opened query 'PV Query: As per the concomitant section of CRF, the subject was started on oxycodone for invasive thymoma on 31 Jan 2021. But the event stop date reported is 21 Jan 2021. Please reconcile the event stop date according to the treatment given, or please state the reason to start treatment after the event recovered. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:01:51
User opened query 'IQVIA Medical request: Please clarify reason for recent surgery that caused hematoma of spleen as noted in the source document narrative.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:45:47
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 09:44:23
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:05:16

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:04:42
User opened query 'PV Query: If subject has a history of invasive thymoma, please update eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:04:31
User opened query 'PV Re-Query: Please provide the treatment medication given for the event. If none, please state so. Please leave open until receipt of hospital records.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:03:56
User closed query 'PV Query: Please provide the treatment medication given for the event. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 16:46:47
User closed query 'PV Query: Please specify the underlying condition for which the procedure of robotic diaphragm plication was performed and if that condition was subject's medical history or it met SAE reporting criteria. Please report accordingly.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 16:46:29
Query 'PV Query: Please provide the treatment medication given for the event. If none, please state so.' answered with 'awaiting hospital DC records' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:34:04
Query 'PV Query: Please specify the underlying condition for which the procedure of robotic diaphragm plication was performed and if that condition was subject's medical history or it met SAE reporting criteria. Please report accordingly.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:33:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:49:20
User opened query 'PV Query: Please provide the treatment medication given for the event. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 14:37:47

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please specify the underlying condition for which the procedure of robotic diaphragm plication was performed and if that condition was subject's medical history or it met SAE reporting criteria. Please report accordingly.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 14:36:48
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	08 Feb 2021 17:22:59
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	08 Feb 2021 17:22:59
User entered 'Subject had procedure to have robotic diaphragm plication and the procedure knicked her spleen and caused her to be placed in icu for 4 out of the 8 she was hospitalized. medical records request was sent.' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:22:59
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	08 Feb 2021 17:18:53
User entered empty.	Diana Toney (b) (4) (b) (4)	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 17:18:53

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:49:42
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 13:43:38
User entered 'USA-US104-2021-mRNA-1273-P301000009'	System	09 Feb 2021 13:43:34
User entered 'New'	(b) (4), (b) (6)	09 Feb 2021 13:43:34

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:34:30
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 19:34:30
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:49:44
User coded data point as SOC: Investigations, HLT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: Norovirus test positive, LLT: Norovirus test positive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 19:00:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 19:00:35
Data point term sent to Coder	System	08 Feb 2021 18:59:56
User entered 'norovirus'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:49:47
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:49:49
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:49:53
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 17:33:29
DataPoint Un-verified.	Diana Toney (b) (4) (b) (4)	27 Apr 2021 17:16:24
User entered '31 Jan 2021' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	27 Apr 2021 17:16:24
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:42:45
User closed query 'PV Query: Onset date is given as 31 Jan 2021 but hospital record indicates that subject was symptomatic 1 week prior to presentation at emergency room. Please consider revising onset date.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 17:23:49
Query 'PV Query: Onset date is given as 31 Jan 2021 but hospital record indicates that subject was symptomatic 1 week prior to presentation at emergency room. Please consider revising onset date.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:20:29
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:20
User entered '23 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:20:20
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:09
User opened query 'PV Query: Onset date is given as 31 Jan 2021 but hospital record indicates that subject was symptomatic 1 week prior to presentation at emergency room. Please consider revising onset date.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 13:37:19
User entered '31 Jan 2021'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:11
User entered empty.	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:12
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:14
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 09:05:10
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	Diana Toney (b) (4) (b) (4)	08 Feb 2021 19:00:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Feb 2021 18:59:50
User entered '04 Feb 2021'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:16
User entered empty.	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:18
Query 'PV Query: Since the subject was hospitalized for the event of norovirus, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:56:41
User opened query 'PV Query: Since the subject was hospitalized for the event of norovirus, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 13:08:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:21
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:25
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:27
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 17:24:02
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'sent' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:25:08
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:28
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 13:08:29
User entered 'I'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:30
User entered '31 Jan 2021'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:41
User entered '04 Feb 2021'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:45
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:46
User entered empty.	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:48
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:50
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:51
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:55
User entered 'Not Related (NOT RELATED)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:06:56
User entered 'Not Related (NOT RELATED)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:42:52
User closed query 'PV Query: As the last dose of [study drug] was given on 22 Sep 2020, please update the action taken with [study drug] from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:16:54
Query 'PV Query: As the last dose of [study drug] was given on 22 Sep 2020, please update the action taken with [study drug] from none to not applicable.' answered with 'updated' (Site from Safety).	Amber Vasquez (b) (4) (b) (4)	16 Apr 2021 17:22:08
DataPoint Un-verified.	Amber Vasquez (b) (4) (b) (4)	16 Apr 2021 17:22:02
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	16 Apr 2021 17:22:02
User opened query 'PV Query: As the last dose of [study drug] was given on 22 Sep 2020, please update the action taken with [study drug] from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:15:55
User closed query 'Source indicates this is "none". Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 13:31:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:31:47
Query 'Source indicates this is "none". Please confirm and revise if necessary.' answered with 'this is correct. Not related to IP' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:20:20
User opened query 'Source indicates this is "none". Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:07:11
User entered 'Not Applicable (NOT APPLICABLE)'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:07:14
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Can the indications for the concomitant medications acetaminophen/oxycodone, oxybutynin, venlafaxine, and sertraline be provided?' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 17:24:33
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 17:24:20
Query 'PV Query: Can the indications for the concomitant medications acetaminophen/oxycodone, oxybutynin, venlafaxine, and sertraline be provided?' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:49:20
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:49:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:07:18
User opened query 'PV Query: Can the indications for the concomitant medications acetaminophen/oxycodone, oxybutynin, venlafaxine, and sertraline be provided?' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 13:36:52
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 13:08:42
User entered 'I'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:07:19
User entered '0'	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Source indicates this is recovered/resolved. Please confirm and revise if necessary.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:32:15
User closed query 'PV Query: The event end date of 04 Feb 2021 was provided, but the outcome was provided as Unknown. Please confirm if the event resolved on 04 Feb 2021. If yes, please update the event outcome as such. If the event is still ongoing, please remove the event end date.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:32:12
Query 'Source indicates this is recovered/resolved. Please confirm and revise if necessary.' answered with 'confirmed per hospital DC note' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:31:42
Query 'PV Query: The event end date of 04 Feb 2021 was provided, but the outcome was provided as Unknown. Please confirm if the event resolved on 04 Feb 2021. If yes, please update the event outcome as such. If the event is still ongoing, please remove the event end date.' answered with 'updated per hospital DC note' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:25:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:25:37
User opened query 'Source indicates this is recovered/resolved. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 15:24:26
User opened query 'PV Query: The event end date of 04 Feb 2021 was provided, but the outcome was provided as Unknown. Please confirm if the event resolved on 04 Feb 2021. If yes, please update the event outcome as such. If the event is still ongoing, please remove the event end date.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 17:07:41
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Diana Toney (b) (4)	16 Feb 2021 13:08:14
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	08 Feb 2021 19:00:21
	Diana Toney (b) (4)	08 Feb 2021 18:59:50
	(b) (4)	

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:07:43
User entered empty.	Diana Toney (b) (4) (b) (4)	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 17:32:17
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'SARS COV2 COVID 19 PCR testing completed on 1/31/21 not detected' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:51:13
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 17:07:45
User entered 'pt stated she went to adventhealth in flagler for viral symptoms and was in hosp from Jan 31 to Feb 4. Will request medical records today'	Diana Toney (b) (4) (b) (4)	16 Feb 2021 13:08:03 08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Feb 2021 18:59:50

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[AEID](#)

Audit	User	Time (GMT)
User entered 'USA-US104-2021-mRNA-1273-P301000017'	System	06 Apr 2021 18:12:48
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 18:12:48

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Mediastinal neoplasms malignant, PT: Thymoma malignant, LLT: Thymoma malignant invasive - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:46:16
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 14:46:16
Data point term sent to Coder	System	05 Apr 2021 14:42:43
User entered 'Invasive Thymoma'	(b) (4), (b) (6) (b) (4)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Dec 2020'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per MM: please provide final outcome and end date when available. (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 09:05:47
Query 'Per MM: please provide final outcome and end date when available. answered with 'ADDED END DATE' (Site from DM).	douglas winter (b) (4) (b) (4)	26 Apr 2021 15:21:28
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	26 Apr 2021 15:20:51
User opened query 'Per MM: please provide final outcome and end date when available. (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:09:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Apr 2021 15:21:15
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Apr 2021 15:21:15
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Apr 2021 15:20:51
User entered '11 Dec 2020' reason for change: Data Entry Error	douglas winter (b) (4)	26 Apr 2021 15:20:51
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	05 Apr 2021 14:43:35
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	05 Apr 2021 14:42:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Apr 2021 15:41:51
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	09 Apr 2021 15:41:51
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Apr 2021 15:40:00
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 09:07:21
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'hospital DC records pending.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 14:43:55
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	05 Apr 2021 14:43:35
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	05 Apr 2021 14:43:35
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Apr 2021 14:43:35
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:43:35

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). User entered '0'	System	05 Apr 2021 14:42:21
	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Dec 2020'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Dec 2020' reason for change: Data Entry Error	douglas winter (b) (4)	09 Apr 2021 15:41:51
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 11:05:37
Query 'Per CDM: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'UPDATED ICU DATA' (Site from DM).	douglas winter (b) (4) (b) (4)	09 Apr 2021 15:41:11
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Apr 2021 15:40:00
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 09:03:12
User opened query 'Per CDM: Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:03:09
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'awaiting hospital DC records' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 14:43:13
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	05 Apr 2021 14:42:21
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered '4' reason for change: Data Entry Error	douglas winter (b) (4)	09 Apr 2021 15:40:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:43:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:43:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:43:35
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:42:21
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:43:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:43:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:43:35
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:42:21
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 22 Sep 2020 please update the action taken with mRNA-1273 from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:21:11
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:43:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 14:43:35
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:43:35
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 14:42:21
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

None

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	26 Apr 2021 15:21:15
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify reason for recent surgery that caused hematoma of spleen as noted in the source document narrative.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:22:05
User opened query 'PV Query: If subject has a history of invasive thymoma, please update eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:21:49
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:21:38
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:21:27
User entered 'invasive thymoma s/p thymectomy with partial left lobectomy on 12/4/20, close hematoma of spleen secondary to recent surgery, elevated hemidiaphragm secondary to phrenic nerve resection during thymectomy'	(b) (4), (b) (6)	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 15:40:00
User entered '0'	System	05 Apr 2021 14:42:21

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLG: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash maculo-papular, LLT: Maculopapular rash - version MedDRA\\23.0.	Coder Import (b) (4)	24 Apr 2021 14:10:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Apr 2021 14:10:03
Data point term sent to Coder	System	24 Apr 2021 14:09:28
User entered 'MACULOPAPULAR RASH'	douglas winter (b) (4)	24 Apr 2021 14:09:17
	(b) (4)	

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

Number of Days in ICU

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

None

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Apr 2021 14:09:17

US3222296

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:58

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Apr 2021 14:09:17

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:14:53
User closed query 'Subject had many con-meds given during hospitalization listed on discharge documentation. Please enter these con-meds on the conmed log and in this CRF.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 17:32:55
Query 'Subject had many con-meds given during hospitalization listed on discharge documentation. Please enter these con-meds on the conmed log and in this CRF.' answered with 'completed' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:17:32
User opened query 'Subject had many con-meds given during hospitalization listed on discharge documentation. Please enter these con-meds on the conmed log and in this CRF.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:16:23
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:22:16
User entered 'No (N)'	Amber Vasquez (b) (4) (b) (4)	10 Oct 2020 00:09:49

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 16:04:01
Data point term sent to Coder	System	15 Oct 2020 14:28:08
User entered 'amoxicillin'	(b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '1000'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 14:27:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 14:27:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 14:27:54
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 14:27:39
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User entered '3'	System	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User entered '1'	System	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:50
User entered '804 (804)'	System	15 Oct 2020 14:27:39

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:02:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:02:32
Data point term sent to Coder	System	15 Oct 2020 14:45:46
User entered 'zithromax'	(b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'pneumonia'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '250'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	15 Oct 2020 14:46:20
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	15 Oct 2020 14:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:46:20
User entered 'take two pills day one 500mg day 2-5 take one pill 250mg'	(b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'take two pills day one 500mg day 2-5 take one pill 250mg'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:37:12
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	15 Oct 2020 14:47:12
User entered '27 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 14:47:12
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	15 Oct 2020 14:45:46
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User entered empty.	System	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User entered empty.	System	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:11:54
User entered empty.	System	15 Oct 2020 14:45:46

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 14:26:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 14:26:39
Data point term sent to Coder	System	05 Apr 2021 12:52:42
User entered 'Metoprolol'	(b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'HTN'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '0.125'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 12:51:48

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Apr 2021 14:13:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Apr 2021 14:13:03
Data point term sent to Coder Coding entries removed.	System douglas winter (b) (4)	24 Apr 2021 14:11:29 24 Apr 2021 14:11:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Apr 2021 09:15:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Apr 2021 09:15:03
Data point term sent to Coder Coding entries removed.	System douglas winter (b) (4)	09 Apr 2021 15:48:07 09 Apr 2021 15:47:33
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Apr 2021 13:09:01

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. Data point term sent to Coder User entered 'pREDNISONONE'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	05 Apr 2021 13:09:01 05 Apr 2021 12:56:46 05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User closed query 'Per CDM RQ: Kindly update the location and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 10:41:41
Query 'Per CDM RQ: Kindly update the location and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' answered with 'ADDED AE LOG LINE' (Site from DM).	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:11:21
User entered 'AE # 5 MACULOPAPULAR' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:11:07
User opened query 'Per CDM RQ: Kindly update the location and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:17:23
Query 'Per CDM RQ: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:17:07
User opened query 'Per CDM RQ: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:13:47
User closed query 'Per CDM: Please review Indication and update to specify the 'location' and 'type' of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:13:47

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please review Indication and update to specify the 'location' and 'type' of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'CORRECTED' (Site from DM).	douglas winter (b) (4) (b) (4)	09 Apr 2021 15:47:40
User entered 'Maculopapular' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Apr 2021 15:47:33
User opened query 'Per CDM: Please review Indication and update to specify the 'location' and 'type' of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:06:14
User entered 'rash'	(b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '4'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Dose pack decreasing dosage over 6 days'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User entered empty.	System	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User entered empty.	System	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:00
User entered empty.	System	05 Apr 2021 12:55:54

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Apr 2021 14:30:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Apr 2021 14:30:58
Data point term sent to Coder Coding entries removed.	System douglas winter (b) (4)	24 Apr 2021 14:12:29 24 Apr 2021 14:11:39
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Apr 2021 07:50:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Apr 2021 07:50:44
Data point term sent to Coder Coding entries removed.	System douglas winter (b) (4)	09 Apr 2021 15:48:07 09 Apr 2021 15:47:59
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Apr 2021 13:11:56

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. Data point term sent to Coder User entered 'triamcinolone'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	05 Apr 2021 13:11:56 05 Apr 2021 13:09:52 05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User closed query 'Per CDM RQ: Kindly update the location and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 10:41:55
Query 'Per CDM RQ: Kindly update the location and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' answered with 'ADDED AE LOG LINE' (Site from DM).	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:11:51
User entered 'AE # 5 MACULOPAPULAR' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	24 Apr 2021 14:11:39
User opened query 'Per CDM RQ: Kindly update the location and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:16:45
User closed query 'Per CDM: Please review Indication and update to specify the 'location' and 'type' of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:16:45
Query 'Per CDM: Please review Indication and update to specify the 'location' and 'type' of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'CORRECTED' (Site from DM).	douglas winter (b) (4) (b) (4)	09 Apr 2021 15:48:08
User entered 'Maculopapular' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Apr 2021 15:47:59

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please review Indication and update to specify the 'location' and 'type' of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM). User entered 'rash'	(b) (4), (b) (6)	06 Apr 2021 09:06:25
	(b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '0.025%'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'topical cream'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User entered '4'	System	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User entered '1'	System	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:12:04
User entered '804 (804)'	System	05 Apr 2021 13:09:03

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 09:08:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 09:08:54
Data point term sent to Coder	System	09 Apr 2021 16:04:40
Data point term sent to Coder	System	09 Apr 2021 16:00:32
Coding entries removed.	douglas winter (b) (4) (b) (4)	09 Apr 2021 15:59:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:28:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:28:20
Data point term sent to Coder	System	05 Apr 2021 13:27:05
User entered 'oxycodone'	(b) (4), (b) (6) (b) (4)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User closed query 'Per CDM: Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:18:20
Query 'Per CDM: Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'SECONDARY TO THYMECTOMY, SPLENIC INJURY DURING ROBOTIC ASSISTED DIAPHRAGM PTICATION.' (Site from DM).	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:04:35
User entered 'AE 2 INVASIVE THYMOMA' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:04:30
User entered 'AE 3 2 INVASIVE THYMOMA' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Apr 2021 15:59:55
User opened query 'Per CDM: Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:07:08
User entered 'pain'	(b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '325/5'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	05 Apr 2021 13:26:53
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	05 Apr 2021 13:26:29
User entered 'as needed (PRN)'	(b) (4), (b) (6) [Redacted]	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty; reason for change Data Entry Error	(b) (4)	05 Apr 2021 13:26:53
User entered 'Q4H PRN'	(b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 13:26:29

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 13:30:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:30:21
Data point term sent to Coder	System	05 Apr 2021 13:29:06
User entered 'oxybutynin'	(b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'overactive bladder'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '5'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 13:28:38

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 13:33:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:33:25
Data point term sent to Coder	System	05 Apr 2021 13:32:09
User entered 'venlafaxine'	(b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'anxiety'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '75'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 13:31:20

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 13:37:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:37:15
Data point term sent to Coder	System	05 Apr 2021 13:36:25
User entered 'zoloft'	(b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'depression'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '100'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 13:35:15

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:05:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:23:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User closed query 'SAE hospital records from 04Feb2021 discharge indicate subject had a thymectomy on 04Dec2020. Please record this concomitant procedure in the source and in this CRF.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:33:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:33:03
Query 'SAE hospital records from 04Feb2021 discharge indicate subject had a thymectomy on 04Dec2020. Please record this concomitant procedure in the source and in this CRF.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 13:53:28
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 13:53:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:53:23
User opened query 'SAE hospital records from 04Feb2021 discharge indicate subject had a thymectomy on 04Dec2020. Please record this concomitant procedure in the source and in this CRF.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:14:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Oct 2020 00:09:23

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:58

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '04 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:54:05

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'CT Chest'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:54:05

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:54:05

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:58

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:54:05

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:55:52

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'thymectomy'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:55:52

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:55:52

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:05:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:55:52

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:05:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Apr 2021 13:59:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 13:59:34
User entered '31 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:59:34
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 13:59:05
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 13:59:05

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:05:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'CT abdomen and pelvis'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:59:05

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:05:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4)	05 Apr 2021 13:59:34
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	05 Apr 2021 13:59:05
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	05 Apr 2021 13:59:05

US3222296

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:05:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:59:34
User entered 'sepsis'	(b) (4), (b) (6)	05 Apr 2021 13:59:05

US3222296

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:58

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:16
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered '12 Feb 2021' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	12 Apr 2021 15:01:21
User entered '1 Apr 2021'	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:10:22

US3222296

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:58

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:16
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:10:22

US3222296

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'SUBJECTS HAS MUCH TO CONTEND WITH HER MEDICAL HISTORY AND DOESNT WANT TO CONTINUE IN THE TRIAL'	(b) (4) douglas winter (b) (4) (b) (4)	09 Apr 2021 16:10:22

US3222296

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:58

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:16
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered empty.	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:10:22

US3222296

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:58

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:16
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered empty.	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:10:22

US3222296

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:58

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:16
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered empty.	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:10:22

US3222296

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:58

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:42:16
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 14:04:47
User entered empty.	douglas winter (b) (4) (b) (4)	09 Apr 2021 16:10:22

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'USA-US104-2021-MRNA-1273-P301000008'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Teresa'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Becker'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Houston'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:22:04
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:07

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '77081'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:47:28
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	28 Apr 2021 14:55:30
User entered '5'	System	26 Apr 2021 15:22:01
User entered '4'	System	19 Apr 2021 17:49:06
User entered '3'	System	12 Apr 2021 14:12:50
User entered '2'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'USA-US104-2021-MRNA-1273-P301000008'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Teresa'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Becker'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Houston'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:22:04
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:07

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '77081'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:47:28
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	28 Apr 2021 14:55:30
User entered '5'	System	26 Apr 2021 15:22:01
User entered '4'	System	19 Apr 2021 17:49:06
User entered '3'	System	12 Apr 2021 14:12:50
User entered '2'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:58

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '09/Feb/2021 13:42'	(b) (4) System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:47:28
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '1'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'USA-US104-2021-MRNA-1273-P301000008'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Teresa'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Becker'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Houston'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:22:04
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:07

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '77081'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:47:28
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	28 Apr 2021 14:55:30
User entered '5'	System	26 Apr 2021 15:22:01
User entered '4'	System	19 Apr 2021 17:49:06
User entered '3'	System	12 Apr 2021 14:12:50
User entered '2'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:58

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '06/Apr/2021 12:47'	(b) (4) System	06 Apr 2021 16:47:22

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
User entered '1'	(b) (4), (b) (6)	06 Apr 2021 16:47:22

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'USA-US104-2021-MRNA-1273-P301000008'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Teresa'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Becker'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Houston'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:22:04
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:07

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '77081'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:47:28
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	28 Apr 2021 14:55:30
User entered '5'	System	26 Apr 2021 15:22:01
User entered '4'	System	19 Apr 2021 17:49:06
User entered '3'	System	12 Apr 2021 14:12:50
User entered '2'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:58

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '12/Apr/2021 10:12'	(b) (4) System	12 Apr 2021 14:12:50

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:49:25
User entered '1'	(b) (4), (b) (6)	12 Apr 2021 14:12:50

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'USA-US104-2021-MRNA-1273-P301000008'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Teresa'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Becker'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Houston'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:22:04
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:07

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '77081'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:47:28
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	28 Apr 2021 14:55:30
User entered '5'	System	26 Apr 2021 15:22:01
User entered '4'	System	19 Apr 2021 17:49:06
User entered '3'	System	12 Apr 2021 14:12:50
User entered '2'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:58

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '19/Apr/2021 13:48'	(b) (4) System	19 Apr 2021 17:49:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:49:25
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 17:49:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'USA-US104-2021-MRNA-1273-P301000008'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Teresa'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Becker'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Houston'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:22:04
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:07

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '77081'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:47:28
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	28 Apr 2021 14:55:30
User entered '5'	System	26 Apr 2021 15:22:01
User entered '4'	System	19 Apr 2021 17:49:06
User entered '3'	System	12 Apr 2021 14:12:50
User entered '2'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:05:58

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:36
User entered '26/Apr/2021 11:21'	System	26 Apr 2021 15:22:01

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:22:04
User entered '1'	(b) (4), (b) (6)	26 Apr 2021 15:22:01

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'USA-US104-2021-MRNA-1273-P301000008'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Yes (Y)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'No (N)'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Teresa'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Becker'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered 'Houston'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:22:04
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:07

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:47:28
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:42:00
User entered '77081'	System	09 Feb 2021 13:41:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:47:28
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	28 Apr 2021 14:55:30
User entered '5'	System	26 Apr 2021 15:22:01
User entered '4'	System	19 Apr 2021 17:49:06
User entered '3'	System	12 Apr 2021 14:12:50
User entered '2'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:42:06

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:05:58

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
User entered '28/Apr/2021 07:55'	(b) (4) System	28 Apr 2021 14:55:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 14:55:30

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'USA-US104-2021-MRNA-1273-P301000009'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Yes (Y)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Yes (Y)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Teresa'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Becker'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Houston'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:42
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:17

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered '77081'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:33:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 18:43:11
User entered '3'	System	19 Apr 2021 17:19:16
User entered '2'	System	06 Apr 2021 17:33:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'USA-US104-2021-MRNA-1273-P301000009'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Yes (Y)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Yes (Y)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Teresa'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Becker'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Houston'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:42
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:17

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered '77081'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:33:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 18:43:11
User entered '3'	System	19 Apr 2021 17:19:16
User entered '2'	System	06 Apr 2021 17:33:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:58

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '09/Feb/2021 13:44'	(b) (4) System	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:33:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered '1'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'USA-US104-2021-MRNA-1273-P301000009'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Yes (Y)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Yes (Y)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Teresa'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Becker'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Houston'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:42
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:17

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered '77081'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:33:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 18:43:11
User entered '3'	System	19 Apr 2021 17:19:16
User entered '2'	System	06 Apr 2021 17:33:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:58

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '06/Apr/2021 13:33'	(b) (4) System	06 Apr 2021 17:33:10

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
User entered '1'	(b) (4), (b) (6)	06 Apr 2021 17:33:10

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'USA-US104-2021-MRNA-1273-P301000009'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Yes (Y)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Yes (Y)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Teresa'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Becker'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Houston'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:42
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:17

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered '77081'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:33:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 18:43:11
User entered '3'	System	19 Apr 2021 17:19:16
User entered '2'	System	06 Apr 2021 17:33:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:58

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '19/Apr/2021 13:19'	(b) (4) System	19 Apr 2021 17:19:16

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:19:22
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 17:19:16

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'USA-US104-2021-MRNA-1273-P301000009'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Yes (Y)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Yes (Y)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'No (N)'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Bruce'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Teresa'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Rankin'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Becker'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '860 Peachwood Ave'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered '6550 Mapleridge Street'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered 'Deland'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered 'Houston'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:42
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:17

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:33:21
Un-reviewed for Safety.	System	06 Apr 2021 16:47:22
Signature has been broken.	System	06 Apr 2021 16:47:22
User entered '32720'	System	06 Apr 2021 16:47:22
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:43:57
User entered '77081'	System	09 Feb 2021 13:43:34

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:33:21
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
User entered 'US'	(b) (4) System	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 18:43:11
User entered '3'	System	19 Apr 2021 17:19:16
User entered '2'	System	06 Apr 2021 17:33:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:37:12
	(b) (4)	
User entered '1'	System	09 Feb 2021 13:44:02

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:58

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
User entered '27/Apr/2021 14:43'	(b) (4) System	27 Apr 2021 18:43:11

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:43:11

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'USA-US104-2021-MRNA-1273-P301000017'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Bruce'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Rankin'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '860 Peachwood Ave'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Deland'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:27

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '32720'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'US'	(b) (4) System	06 Apr 2021 18:14:03

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 20:09:03
User entered '1'	System	06 Apr 2021 18:14:03

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'USA-US104-2021-MRNA-1273-P301000017'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Bruce'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Rankin'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '860 Peachwood Ave'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Deland'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:27

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '32720'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'US'	(b) (4) System	06 Apr 2021 18:14:03

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 20:09:03
User entered '1'	System	06 Apr 2021 18:14:03

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:58

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '06/Apr/2021 14:13'	(b) (4) System	06 Apr 2021 18:14:03

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '1'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:14:03

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'USA-US104-2021-MRNA-1273-P301000017'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Yes (Y)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'No (N)'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Bruce'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Rankin'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '860 Peachwood Ave'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'Deland'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
Signature has been broken.	System	26 Apr 2021 15:22:01
User entered empty.	System	26 Apr 2021 15:22:01
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'FL'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 19:41:27

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered '32720'	(b) (4) System	06 Apr 2021 18:12:48

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:04:47
User entered 'US'	(b) (4) System	06 Apr 2021 18:14:03

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 20:09:03
User entered '1'	System	06 Apr 2021 18:14:03

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:46
User entered '26/Apr/2021 16:08'	System	26 Apr 2021 20:09:03

US3222296

Folder: SAE USA-US104-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 20:09:22
User entered '1'	(b) (4), (b) (6)	26 Apr 2021 20:09:03