

US3002046 (Prod: Meridian Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 08:40:41

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US3002046

Form: Participant Creation

Generated On: 26 Nov 2020 08:40:41

[Participant ID](#)

US3002046

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

US3002046

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

Date of Birth (MMM yyyy)	(b) (6) 1959
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

Generated On: 26 Nov 2020 08:40:41

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:40:41

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:40:41

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

Condition	POST- MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	13:26 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 13:26
Height (<i>xxx.x</i>)	167 cm
Weight (<i>xxx.x</i>)	88.1 kg
BMI (<i>xxx.x</i>)	31.58952 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

Generated On: 26 Nov 2020 08:40:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 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

Generated On: 26 Nov 2020 08:40:41

Date of assessment (<i>dd MMM yyyy</i>)	29 JUL 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input type="radio"/>
	Post-menopausal <input checked="" type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2010
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Other	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	True
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

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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

Generated On: 26 Nov 2020 08:40:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

What was the date of randomization? (dd MMM yyyy) 29 JUL 2020

What was the participant's randomization number? 100184

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JUL 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 13:26
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JUL 2020
Time of assessment (00:00-23:59)	15:12 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 15:12
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 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

Generated On: 26 Nov 2020 08:40:41

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	29 JUL 2020
What was the treatment time? (00:00-23:59)	14:40 (24 HR)
Treatment Date and Time (derived)	29 JUL 2020 14:40
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
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

Generated On: 26 Nov 2020 08:40:41

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

29 JUL 2020

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

14:05 (24 HR)

Collection date and time (derived)

29 JUL 2020 14:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:40:41

Collection date (<i>dd MMM yyyy</i>)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:46	29 JUL 2020 13:46
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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: 26 Nov 2020 08:40:41

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

29 JUL 2020 15:10

PC Open Date & Time

29 JUL 2020 15:00

PC Close Date & Time

29 JUL 2020 17:30

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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 97.7 °F

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

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

PC Time Stamp	29 JUL 2020 18:25
PC Open Date & Time	29 JUL 2020 18:25
PC Close Date & Time	30 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 13:21

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 12:04

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 12:01

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 17:44

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 12:02

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 12:23

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

29 JUL 2020 15:11

PC Open Date & Time

29 JUL 2020 15:00

PC Close Date & Time

29 JUL 2020 17:30

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

29 JUL 2020 18:26

PC Open Date & Time

29 JUL 2020 18:25

PC Close Date & Time

30 JUL 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 13:22

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 12:04

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

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

01 AUG 2020 12:01

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 17:44

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 12:02

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 12:24

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 15:11
PC Open Date & Time	29 JUL 2020 15:00
PC Close Date & Time	29 JUL 2020 17:30

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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 ☐

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 18:26
PC Open Date & Time	29 JUL 2020 18:25
PC Close Date & Time	30 JUL 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

		Yes <input type="checkbox"/>
PC Time stamp	30 JUL 2020 13:22	
PC Open Date & Time	30 JUL 2020 12:00	
PC Close Date & Time	31 JUL 2020 11:59	

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 12:05
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 12:02
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 17:44
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 12:03
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

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 ☒

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 12:24
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3002046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

Was Contact Attempted?

Yes ☒

No ☐

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

05 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

Was Contact Attempted?

Yes ☒

No ☐

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

22 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3002046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

Was this visit performed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Visit date (dd MMM yyyy)	
--------------------------	--

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input type="radio"/>

Folder OID	VISIT2
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US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

US3002046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

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.

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3002046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

Was the sample collected?

Yes ☐
No ☒

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:40:41

Collection date (*dd MMM yyyy*)

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

US3002046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

US3002046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

US3002046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 OCT 2020 17:54:35
Patient Cloud Open Date & Time	28 SEP 2020 00:01
Patient Cloud Close Date & Time	02 OCT 2020 23:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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

06 OCT 2020 17:43:42

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 10:18:53

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 13:57:20

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 10:39:27

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3002046

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 08:40:41

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"/>

US3002046

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 08:40:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3002046

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:40:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

AEID	USA-US005-2020-MRNA-1273-P30 1000001
Adverse event	LEFT BROKEN HIP
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)	12 AUG 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)	14 AUG 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)	12 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	81 of 754

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" 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	PT. WAS WALKING HER DOG AND TRIPPED AND BROKE HER LEFT HIP. PATIENT WENT TO BERGAN MERCY ER AND HAD SURGERY. MEDICAL RECORDS ARE PENDING.
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

v6.020 DTW (1102)

82 of 754

US3002046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:40:41

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

Yes ☐

No ☒

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

US3002046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:40:41

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3002046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 08:40:41

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
14 AUG 2020	LEFT HIP FRACTURE REPAIR	Adverse Event	

US3002046

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:40:41

Date of dosing discontinuation (dd MMM yyyy)

06 NOV 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☒

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

PT. BROKE HER HIP AND NO
LONGER WANTED TO BE IN
THE STUDY. MEDICAL
RECORDS ARE STILL PENDING
SAEID-USA-US005-2020-MRNA-1
273-P301000001

US3002046

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:40:41

Date of study discontinuation/completion (*dd MMM yyyy*) 06 NOV 2020

Reason for discontinuation

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

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

PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1 273-P301000001

If reason for discontinuation is Death, main cause of death

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

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

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

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:40:41

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	07/SEP/2020 13:06
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

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:40:41

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/SEP/2020 09:07
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

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:40:41

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	13/NOV/2020 10:43
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

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:40:41

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	21/NOV/2020 02:12
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

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:40:41

SAEID	USA-US005-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/NOV/2020 14:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3002046 (Prod: Meridian Clinical Research)

US3002046

Form: Participant Creation

Generated On: 26 Nov 2020 08:40:41

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3002046'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	29 Jul 2020 18:54:57

US3002046

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:34:16

US3002046

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Jul 2020 18:54:58

US3002046

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Jul 2020 14:34:16

US3002046

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	30 Jul 2020 14:34:16

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered (b) (6) 1959'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Jul 2020 18:54:59

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Age](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '60'	System	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[White](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:41

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:34:33

US3002046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Jul 2020'	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2020'	System	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:01:40

US3002046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Jul 2020 18:54:58

US3002046

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:40:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:00:41
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:34:57

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

Condition

Audit	User	Time (GMT)
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)	10 Nov 2020 13:27:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 13:27:35
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:03:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:03:05
Data point term sent to Coder	System	14 Sep 2020 16:02:10
User entered 'post- menopausal'	(b) (4), (b) (6) (b) (4)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '2010'	System	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:01:22

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '13:26'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 13:26'	System	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '167' cm	(b) (4), (b) (6)	30 Jul 2020 14:36:04
DataPoint set to visible.	System	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '88.1' kg	(b) (4), (b) (6)	30 Jul 2020 14:36:04
DataPoint set to visible.	System	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '31.58952'	System	16 Sep 2020 23:38:20
User entered '31.6'	System	30 Jul 2020 14:36:04
DataPoint set to visible.	System	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	30 Jul 2020 14:36:04
DataPoint set to visible.	System	29 Jul 2020 20:01:44

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:16:50
User entered '37.0' C	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:16:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:16:50
User entered '81'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:16:50
User entered '16'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:16:50
User entered '126'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:16:50
User entered '76'	(b) (4), (b) (6)	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Jul 2020 14:36:04

US3002046

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:36:15

US3002046

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:36:15

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 03:00:58
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'will update MH' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:00:24
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 10:09:26
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:40:41

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:36:36

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

Other

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 16:51:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 16:51:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Aug 2020 16:51:02
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Jul 2020 14:35:22
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

No Risk Identified

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

Other

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:41

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:35:22

US3002046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:36:50

US3002046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:36:50

US3002046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Jul 2020 14:36:50

US3002046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	30 Jul 2020 14:36:50

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	29 Jul 2020 19:20:51

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:16:50
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:16:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 19:20:51
User entered '100184' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Jul 2020 19:20:51

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Jul 2020 19:20:51

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:37:11

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:37:11

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:37:11

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:37:11

US3002046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:41

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:37:11

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:18:28
User entered '167' cm	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:18:28
User entered '88.1' kg	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:18:28
User entered '167' cm	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:18:28
User entered '88.1' kg	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '13:26'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 13:26'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:18:28
User entered '167' cm	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:41

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:18:28
User entered '88.1' kg	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	04 Aug 2020 16:06:39
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		30 Jul 2020 14:38:19
User entered '15:12'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 15:12'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.9' C	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '120'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '83'	(b) (4), (b) (6)	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Jul 2020 14:38:19

US3002046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:38:31

US3002046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:38:31

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Jul 2020'	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '14:40'	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 14:40'	System	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jessica Satorie (b) (4) (b) (4)	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 20:02:05

US3002046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:38:56

US3002046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:38:56

US3002046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '14:05'	(b) (4), (b) (6)	30 Jul 2020 14:38:56

US3002046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 14:05'	System	30 Jul 2020 14:38:56

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:40:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Jul 2020'	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:46'	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 13:46'	System	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	30 Jul 2020 14:39:26

US3002046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 14:40:29

US3002046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Jul 2020 14:40:29

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:09:40', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd9ca1bd3-5eee-4b95-9b06-097478dc0913'	System	29 Jul 2020 20:10:04
User entered 'Yes (Y)'	System	29 Jul 2020 20:10:04

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:09:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd9ca1bd3-5eee-4b95-9b06-097478dc0913'	System	29 Jul 2020 20:10:04
User entered '98.4'	System	29 Jul 2020 20:10:04

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:09:53', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd9ca1bd3-5eee-4b95-9b06-097478dc0913'	System	29 Jul 2020 20:10:04
User entered 'No (N)'	System	29 Jul 2020 20:10:04

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:10:02', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd9ca1bd3-5eee-4b95-9b06-097478dc0913'	System	29 Jul 2020 20:10:04
User entered '29 Jul 2020 15:10'	System	29 Jul 2020 20:10:04

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 15:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 17:30'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:31', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd6555243-7a89-411f-8765-0aa72e210808'	System	29 Jul 2020 23:25:53
User entered 'Yes (Y)'	System	29 Jul 2020 23:25:53

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:39', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd6555243-7a89-411f-8765-0aa72e210808'	System	29 Jul 2020 23:25:53
User entered '97.7'	System	29 Jul 2020 23:25:53

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:43', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd6555243-7a89-411f-8765-0aa72e210808'	System	29 Jul 2020 23:25:53
User entered 'No (N)'	System	29 Jul 2020 23:25:53

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd6555243-7a89-411f-8765-0aa72e210808'	System	29 Jul 2020 23:25:53
User entered '29 Jul 2020 18:25'	System	29 Jul 2020 23:25:53

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 18:25'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 2'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:21:23', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f183dce4-3c6d-4f90-8cd3-0a523387dd05'	System	30 Jul 2020 18:21:57
User entered 'Yes (Y)'	System	30 Jul 2020 18:21:57

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:21:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f183dce4-3c6d-4f90-8cd3-0a523387dd05'	System	30 Jul 2020 18:21:57
User entered '97.3'	System	30 Jul 2020 18:21:57

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:21:52', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f183dce4-3c6d-4f90-8cd3-0a523387dd05'	System	30 Jul 2020 18:21:57
User entered 'No (N)'	System	30 Jul 2020 18:21:57

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:21:55', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f183dce4-3c6d-4f90-8cd3-0a523387dd05'	System	30 Jul 2020 18:21:57
User entered '30 Jul 2020 13:21'	System	30 Jul 2020 18:21:57

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 3'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:21', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '55b9308e-b944-42a8-b1eb-ad27b13133f7'	System	31 Jul 2020 17:04:38
User entered 'Yes (Y)'	System	31 Jul 2020 17:04:38

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:27', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '55b9308e-b944-42a8-b1eb-ad27b13133f7'	System	31 Jul 2020 17:04:38
User entered '98.5'	System	31 Jul 2020 17:04:38

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:31', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '55b9308e-b944-42a8-b1eb-ad27b13133f7'	System	31 Jul 2020 17:04:38
User entered 'No (N)'	System	31 Jul 2020 17:04:38

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:37', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '55b9308e-b944-42a8-b1eb-ad27b13133f7'	System	31 Jul 2020 17:04:38
User entered '31 Jul 2020 12:04'	System	31 Jul 2020 17:04:38

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 4'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:04', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0d56706-16de-459d-8a8f-ad824b3ecd82'	System	01 Aug 2020 17:01:37
User entered 'Yes (Y)'	System	01 Aug 2020 17:01:37

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:19', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0d56706-16de-459d-8a8f-ad824b3ecd82'	System	01 Aug 2020 17:01:37
User entered '97.8'	System	01 Aug 2020 17:01:37

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:32', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0d56706-16de-459d-8a8f-ad824b3ecd82'	System	01 Aug 2020 17:01:37
User entered 'No (N)'	System	01 Aug 2020 17:01:37

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:35', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0d56706-16de-459d-8a8f-ad824b3ecd82'	System	01 Aug 2020 17:01:37
User entered '01 Aug 2020 12:01'	System	01 Aug 2020 17:01:37

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 5'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:01', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd0ed2663-11cb-43b8-a234-7b5c9e99509c'	System	02 Aug 2020 22:44:17
User entered 'Yes (Y)'	System	02 Aug 2020 22:44:17

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:06', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd0ed2663-11cb-43b8-a234-7b5c9e99509c'	System	02 Aug 2020 22:44:17
User entered '97.8'	System	02 Aug 2020 22:44:17

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:09', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd0ed2663-11cb-43b8-a234-7b5c9e99509c'	System	02 Aug 2020 22:44:17
User entered 'No (N)'	System	02 Aug 2020 22:44:17

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:15', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'd0ed2663-11cb-43b8-a234-7b5c9e99509c'	System	02 Aug 2020 22:44:17
User entered '02 Aug 2020 17:44'	System	02 Aug 2020 22:44:17

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 6'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:01:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '904fc65f-6272-4345-a2d2-57ae38e41d4f'	System	03 Aug 2020 17:02:03
User entered 'Yes (Y)'	System	03 Aug 2020 17:02:03

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:01:54', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '904fc65f-6272-4345-a2d2-57ae38e41d4f'	System	03 Aug 2020 17:02:03
User entered '98.1'	System	03 Aug 2020 17:02:03

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:01:58', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '904fc65f-6272-4345-a2d2-57ae38e41d4f'	System	03 Aug 2020 17:02:03
User entered 'No (N)'	System	03 Aug 2020 17:02:03

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:02', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '904fc65f-6272-4345-a2d2-57ae38e41d4f'	System	03 Aug 2020 17:02:03
User entered '03 Aug 2020 12:02'	System	03 Aug 2020 17:02:03

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 7'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:21', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'ee792d60-ce51-4854-a0da-0050150facal' User entered 'Yes (Y)'	System	04 Aug 2020 17:23:49

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:33', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'ee792d60-ce51-4854-a0da-0050150facal' User entered '97.5'	System	04 Aug 2020 17:23:49

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:45', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'ee792d60-ce51-4854-a0da-0050150facal'	System	04 Aug 2020 17:23:49
User entered 'No (N)'	System	04 Aug 2020 17:23:49

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:48', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'ee792d60-ce51-4854-a0da-0050150facal' User entered '04 Aug 2020 12:23'	System	04 Aug 2020 17:23:49
	System	04 Aug 2020 17:23:49

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:10:47', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '27b1b826-32f9-42e5-a94a-578a197d4fd1'	System	29 Jul 2020 20:11:12
User entered 'None (1)'	System	29 Jul 2020 20:11:12

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:10:57', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '27b1b826-32f9-42e5-a94a-578a197d4fd1'	System	29 Jul 2020 20:11:12
User entered 'No (N)'	System	29 Jul 2020 20:11:12

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:00', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '27b1b826-32f9-42e5-a94a-578a197d4fd1'	System	29 Jul 2020 20:11:12
User entered 'No (N)'	System	29 Jul 2020 20:11:12

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:05', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '27b1b826-32f9-42e5-a94a-578a197d4fd1'	System	29 Jul 2020 20:11:12
User entered 'None (1)'	System	29 Jul 2020 20:11:12

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:09', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '27b1b826-32f9-42e5-a94a-578a197d4fd1'	System	29 Jul 2020 20:11:12
User entered '29 Jul 2020 15:11'	System	29 Jul 2020 20:11:12

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 15:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 17:30'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:53', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '04fe06d0-35a1-4880-b092-64302930e5d8'	System	29 Jul 2020 23:26:07
User entered 'None (1)'	System	29 Jul 2020 23:26:07

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:56', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '04fe06d0-35a1-4880-b092-64302930e5d8'	System	29 Jul 2020 23:26:07
User entered 'No (N)'	System	29 Jul 2020 23:26:07

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:25:58', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '04fe06d0-35a1-4880-b092-64302930e5d8'	System	29 Jul 2020 23:26:07
User entered 'No (N)'	System	29 Jul 2020 23:26:07

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:02', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '04fe06d0-35a1-4880-b092-64302930e5d8'	System	29 Jul 2020 23:26:07
User entered 'None (1)'	System	29 Jul 2020 23:26:07

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:05', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '04fe06d0-35a1-4880-b092-64302930e5d8'	System	29 Jul 2020 23:26:07
User entered '29 Jul 2020 18:26'	System	29 Jul 2020 23:26:07

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 18:25'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 2'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:00', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '5a624398-8aaa-4948-8328-cb50b0cf6c64'	System	30 Jul 2020 18:22:18
User entered 'None (1)'	System	30 Jul 2020 18:22:18

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:05', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '5a624398-8aaa-4948-8328-cb50b0cf6c64'	System	30 Jul 2020 18:22:18
User entered 'No (N)'	System	30 Jul 2020 18:22:18

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:08', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '5a624398-8aaa-4948-8328-cb50b0cf6c64'	System	30 Jul 2020 18:22:18
User entered 'No (N)'	System	30 Jul 2020 18:22:18

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:13', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '5a624398-8aaa-4948-8328-cb50b0cf6c64'	System	30 Jul 2020 18:22:18
User entered 'None (1)'	System	30 Jul 2020 18:22:18

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:16', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '5a624398-8aaa-4948-8328-cb50b0cf6c64'	System	30 Jul 2020 18:22:18
User entered '30 Jul 2020 13:22'	System	30 Jul 2020 18:22:18

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 3'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:42', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'e196e572-0d57-435e-928d-ba1fd64f7d4f'	System	31 Jul 2020 17:04:56
User entered 'None (1)'	System	31 Jul 2020 17:04:56

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:45', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'e196e572-0d57-435e-928d-ba1fd64f7d4f'	System	31 Jul 2020 17:04:56
User entered 'No (N)'	System	31 Jul 2020 17:04:56

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:47', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'e196e572-0d57-435e-928d-ba1fd64f7d4f'	System	31 Jul 2020 17:04:56
User entered 'No (N)'	System	31 Jul 2020 17:04:56

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:51', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'e196e572-0d57-435e-928d-ba1fd64f7d4f'	System	31 Jul 2020 17:04:56
User entered 'None (1)'	System	31 Jul 2020 17:04:56

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:54', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'e196e572-0d57-435e-928d-ba1fd64f7d4f'	System	31 Jul 2020 17:04:56
User entered '31 Jul 2020 12:04'	System	31 Jul 2020 17:04:56

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 4'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:39', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'fad1f9a6-91d6-467c-bc29-4b9885122bb8'	System	01 Aug 2020 17:01:50
User entered 'None (1)'	System	01 Aug 2020 17:01:50

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:42', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'fad1f9a6-91d6-467c-bc29-4b9885122bb8'	System	01 Aug 2020 17:01:50
User entered 'No (N)'	System	01 Aug 2020 17:01:50

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:45', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'fad1f9a6-91d6-467c-bc29-4b9885122bb8'	System	01 Aug 2020 17:01:50
User entered 'No (N)'	System	01 Aug 2020 17:01:50

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:47', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'fad1f9a6-91d6-467c-bc29-4b9885122bb8'	System	01 Aug 2020 17:01:50
User entered 'None (1)'	System	01 Aug 2020 17:01:50

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'fad1f9a6-91d6-467c-bc29-4b9885122bb8'	System	01 Aug 2020 17:01:50
User entered '01 Aug 2020 12:01'	System	01 Aug 2020 17:01:50

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 5'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:20', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '0d4d8da0-4a84-4554-bcfe-1e711bd4b2c5'	System	02 Aug 2020 22:44:36
User entered 'None (1)'	System	02 Aug 2020 22:44:36

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:23', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '0d4d8da0-4a84-4554-bcfe-1e711bd4b2c5'	System	02 Aug 2020 22:44:36
User entered 'No (N)'	System	02 Aug 2020 22:44:36

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:26', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '0d4d8da0-4a84-4554-bcfe-1e711bd4b2c5'	System	02 Aug 2020 22:44:36
User entered 'No (N)'	System	02 Aug 2020 22:44:36

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:30', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '0d4d8da0-4a84-4554-bcfe-1e711bd4b2c5'	System	02 Aug 2020 22:44:36
User entered 'None (1)'	System	02 Aug 2020 22:44:36

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:33', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '0d4d8da0-4a84-4554-bcfe-1e711bd4b2c5'	System	02 Aug 2020 22:44:36
User entered '02 Aug 2020 17:44'	System	02 Aug 2020 22:44:36

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 6'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:27', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '196c1018-230e-433f-a14f-7dad3e01112d'	System	03 Aug 2020 17:02:52
User entered 'None (1)'	System	03 Aug 2020 17:02:52

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:32', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '196c1018-230e-433f-a14f-7dad3e01112d'	System	03 Aug 2020 17:02:52
User entered 'No (N)'	System	03 Aug 2020 17:02:52

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:38', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '196c1018-230e-433f-a14f-7dad3e01112d'	System	03 Aug 2020 17:02:52
User entered 'No (N)'	System	03 Aug 2020 17:02:52

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:42', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '196c1018-230e-433f-a14f-7dad3e01112d'	System	03 Aug 2020 17:02:52
User entered 'None (1)'	System	03 Aug 2020 17:02:52

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:51', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '196c1018-230e-433f-a14f-7dad3e01112d'	System	03 Aug 2020 17:02:52
User entered '03 Aug 2020 12:02'	System	03 Aug 2020 17:02:52

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 7'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:52', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '45784579-c94f-48e2-a08c-040682bca3de'	System	04 Aug 2020 17:24:05
User entered 'None (1)'	System	04 Aug 2020 17:24:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:55', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '45784579-c94f-48e2-a08c-040682bca3de'	System	04 Aug 2020 17:24:05
User entered 'No (N)'	System	04 Aug 2020 17:24:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:23:57', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '45784579-c94f-48e2-a08c-040682bca3de'	System	04 Aug 2020 17:24:05
User entered 'No (N)'	System	04 Aug 2020 17:24:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:00', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '45784579-c94f-48e2-a08c-040682bca3de'	System	04 Aug 2020 17:24:05
User entered 'None (1)'	System	04 Aug 2020 17:24:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:03', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '45784579-c94f-48e2-a08c-040682bca3de'	System	04 Aug 2020 17:24:05
User entered '04 Aug 2020 12:24'	System	04 Aug 2020 17:24:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:15', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f'	System	29 Jul 2020 20:11:37
User entered 'None (0)'	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:17', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f'	System	29 Jul 2020 20:11:37
User entered 'None (0)'	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:20', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f'	System	29 Jul 2020 20:11:37
User entered 'None (0)'	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:22', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f'	System	29 Jul 2020 20:11:37
User entered 'None (0)'	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:25', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f'	System	29 Jul 2020 20:11:37
User entered 'None (0)'	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:27', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f'	System	29 Jul 2020 20:11:37
User entered 'None (0)'	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:32', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f'	System	29 Jul 2020 20:11:37
User entered 'No (N)'	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T15:11:35', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f52d1cba-7454-4686-9f56-5a37bdbcb8f'	System	29 Jul 2020 20:11:37
User entered '29 Jul 2020 15:11'	System	29 Jul 2020 20:11:37

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 15:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 17:30'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:09', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a' User entered 'None (0)'	System	29 Jul 2020 23:26:29
	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:11', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a'	System	29 Jul 2020 23:26:29
User entered 'None (0)'	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:14', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a'	System	29 Jul 2020 23:26:29
User entered 'None (0)'	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:17', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a'	System	29 Jul 2020 23:26:29
User entered 'None (0)'	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:19', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a'	System	29 Jul 2020 23:26:29
User entered 'None (0)'	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:21', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a'	System	29 Jul 2020 23:26:29
User entered 'None (0)'	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:25', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a'	System	29 Jul 2020 23:26:29
User entered 'No (N)'	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-29T18:26:27', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '593348c1-44df-4fa3-95e4-9b86fc0d451a'	System	29 Jul 2020 23:26:29
User entered '29 Jul 2020 18:26'	System	29 Jul 2020 23:26:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 18:25'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 2'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:21', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a'	System	30 Jul 2020 18:22:52
User entered 'None (0)'	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:25', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a'	System	30 Jul 2020 18:22:52
User entered 'None (0)'	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:28', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a'	System	30 Jul 2020 18:22:52
User entered 'None (0)'	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:31', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a'	System	30 Jul 2020 18:22:52
User entered 'None (0)'	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:34', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a'	System	30 Jul 2020 18:22:52
User entered 'None (0)'	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:44', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a'	System	30 Jul 2020 18:22:52
User entered 'None (0)'	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:48', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a'	System	30 Jul 2020 18:22:52
User entered 'No (N)'	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-30T13:22:51', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'f0513923-99a3-43ae-a5f7-b38ae9bd596a'	System	30 Jul 2020 18:22:52
User entered '30 Jul 2020 13:22'	System	30 Jul 2020 18:22:52

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 3'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:04:58', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a'	System	31 Jul 2020 17:05:26
User entered 'None (0)'	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:01', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a'	System	31 Jul 2020 17:05:26
User entered 'None (0)'	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:04', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a'	System	31 Jul 2020 17:05:26
User entered 'None (0)'	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:09', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a'	System	31 Jul 2020 17:05:26
User entered 'None (0)'	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:11', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a'	System	31 Jul 2020 17:05:26
User entered 'None (0)'	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:14', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a'	System	31 Jul 2020 17:05:26
User entered 'None (0)'	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:18', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a'	System	31 Jul 2020 17:05:26
User entered 'No (N)'	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-07-31T12:05:23', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8c65ad19-aa91-4c86-b552-2c2b516bc70a' User entered '31 Jul 2020 12:05'	System	31 Jul 2020 17:05:26
	System	31 Jul 2020 17:05:26

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 4'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:53', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40'	System	01 Aug 2020 17:02:10
User entered 'None (0)'	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:55', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40'	System	01 Aug 2020 17:02:10
User entered 'None (0)'	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:56', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40'	System	01 Aug 2020 17:02:10
User entered 'None (0)'	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:01:58', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40'	System	01 Aug 2020 17:02:10
User entered 'None (0)'	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:02:00', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40'	System	01 Aug 2020 17:02:10
User entered 'None (0)'	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:02:02', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40'	System	01 Aug 2020 17:02:10
User entered 'None (0)'	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:02:05', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40'	System	01 Aug 2020 17:02:10
User entered 'No (N)'	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-01T12:02:08', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'db808020-8592-450f-af66-90ecc65dab40'	System	01 Aug 2020 17:02:10
User entered '01 Aug 2020 12:02'	System	01 Aug 2020 17:02:10

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 5'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:38', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104'	System	02 Aug 2020 22:44:59
User entered 'None (0)'	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:40', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104'	System	02 Aug 2020 22:44:59
User entered 'None (0)'	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:42', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104'	System	02 Aug 2020 22:44:59
User entered 'None (0)'	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:45', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104'	System	02 Aug 2020 22:44:59
User entered 'None (0)'	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:47', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104'	System	02 Aug 2020 22:44:59
User entered 'None (0)'	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:49', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104'	System	02 Aug 2020 22:44:59
User entered 'None (0)'	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:53', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104'	System	02 Aug 2020 22:44:59
User entered 'No (N)'	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-02T17:44:55', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '178759f8-832b-4cb7-a0fa-b143f4bdf104'	System	02 Aug 2020 22:44:59
User entered '02 Aug 2020 17:44'	System	02 Aug 2020 22:44:59

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 6'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:56', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0'	System	03 Aug 2020 17:03:18
User entered 'None (0)'	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:02:58', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0'	System	03 Aug 2020 17:03:18
User entered 'None (0)'	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:00', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0'	System	03 Aug 2020 17:03:18
User entered 'None (0)'	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:02', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0'	System	03 Aug 2020 17:03:18
User entered 'None (0)'	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:04', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0'	System	03 Aug 2020 17:03:18
User entered 'None (0)'	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:06', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0'	System	03 Aug 2020 17:03:18
User entered 'None (0)'	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:10', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0'	System	03 Aug 2020 17:03:18
User entered 'No (N)'	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-03T12:03:16', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '428a6ffa-702e-4ef1-ac85-8c277a964fb0'	System	03 Aug 2020 17:03:18
User entered '03 Aug 2020 12:03'	System	03 Aug 2020 17:03:18

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 7'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:07', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'None (0)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:09', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'None (0)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:11', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'None (0)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:13', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'None (0)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:15', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'None (0)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:19', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'None (0)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:22', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered 'No (N)'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-08-04T12:24:25', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b7bff9ce-67cc-4f25-b4e5-c5cabe55e1f0'	System	04 Aug 2020 17:24:29
User entered '04 Aug 2020 12:24'	System	04 Aug 2020 17:24:29

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 20:02:05

US3002046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:40:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 14:57:36

US3002046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '05 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 14:57:36

US3002046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Aug 2020 14:57:36

US3002046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 14:57:36

US3002046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 14:57:42

US3002046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Aug 2020 14:57:42

US3002046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	30 Sep 2020 16:58:50
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 16:04:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:04:11

US3002046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '12 Aug 2020'	(b) (4), (b) (6)	14 Sep 2020 16:04:11

US3002046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tiffany Nemecek (b) (4)	30 Sep 2020 16:58:50
reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:04:11

US3002046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:04:11

US3002046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:04:16

US3002046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 16:04:16

US3002046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:04:31

US3002046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered '22 Aug 2020'	(b) (4), (b) (6)	14 Sep 2020 16:04:31

US3002046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 16:04:31

US3002046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:04:31

US3002046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:04:35

US3002046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 16:04:35

US3002046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please complete the rest of the forms in the Visit 2 Day 29 folder as these should not remain empty. Thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:10:08
Query 'Per CDM: Please complete the rest of the forms in the Visit 2 Day 29 folder as these should not remain empty. Thank you. ' answered with 'Subject withdrew consent and did not complete visit. Unable to answer past stating NO to was visit performed' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:20:42
User opened query 'Per CDM: Please complete the rest of the forms in the Visit 2 Day 29 folder as these should not remain empty. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:58:58
User entered 'No (N)'	Tiffany Nemecek (b) (4)	22 Sep 2020 03:17:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:17:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:17:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	22 Sep 2020 03:17:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:30:57

US3002046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:31:02

US3002046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:31:02

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

If No, reason not given

Audit	User	Time (GMT)
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		23 Nov 2020 23:53:22
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Nov 2020 23:53:22
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		19 Nov 2020 17:32:18
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:32:18

US3002046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:32:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:32:26

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:40:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:32:38

US3002046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:17:34

US3002046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 03:17:34

US3002046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:18:07

US3002046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:18:07

US3002046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:18:07

US3002046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:18:07

US3002046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:18:24

US3002046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 03:18:24

US3002046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:18:32

US3002046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:18:32

US3002046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:18:32

US3002046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	22 Sep 2020 03:18:32

US3002046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:33:03
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	22 Sep 2020 03:18:38

US3002046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:33:03
User entered '1'	System	22 Sep 2020 03:18:38

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 64'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[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 (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-02T17:54:23', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b2c9bda6-c641-461e-ba2e-7366be6c861a' User entered 'No (N)'	System	02 Oct 2020 22:54:37
	System	02 Oct 2020 22:54:37

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-02T17:54:26', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b2c9bda6-c641-461e-ba2e-7366be6c861a' User entered 'No (N)'	System	02 Oct 2020 22:54:37
	System	02 Oct 2020 22:54:37

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-02T17:54:35', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b2c9bda6-c641-461e-ba2e-7366be6c861a' User entered '02 Oct 2020 17:54:35'	System	02 Oct 2020 22:54:37
	System	02 Oct 2020 22:54:37

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 71'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[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 (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-06T17:43:35', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8b176bc9-9a2a-416e-97fe-e7d035bc6917'	System	06 Oct 2020 22:43:45
User entered 'No (N)'	System	06 Oct 2020 22:43:45

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-06T17:43:39', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8b176bc9-9a2a-416e-97fe-e7d035bc6917'	System	06 Oct 2020 22:43:45
User entered 'No (N)'	System	06 Oct 2020 22:43:45

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-06T17:43:42', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '8b176bc9-9a2a-416e-97fe-e7d035bc6917' User entered '06 Oct 2020 17:43:42'	System	06 Oct 2020 22:43:45
	System	06 Oct 2020 22:43:45

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 78'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[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 (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-16T10:18:44', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '1b4b0afe-3fd6-4649-8007-08ebc602361f'	System	16 Oct 2020 15:18:59
User entered 'No (N)'	System	16 Oct 2020 15:18:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-16T10:18:47', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '1b4b0afe-3fd6-4649-8007-08ebc602361f'	System	16 Oct 2020 15:18:59
User entered 'No (N)'	System	16 Oct 2020 15:18:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-16T10:18:53', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '1b4b0afe-3fd6-4649-8007-08ebc602361f' User entered '16 Oct 2020 10:18:53'	System	16 Oct 2020 15:18:59
	System	16 Oct 2020 15:18:59

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 92'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[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 (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-26T13:57:08', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '641b2b04-31f9-4041-a66e-610e915368a7' User entered 'No (N)'	System	26 Oct 2020 18:57:22
	System	26 Oct 2020 18:57:22

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-26T13:57:12', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '641b2b04-31f9-4041-a66e-610e915368a7'	System	26 Oct 2020 18:57:22
User entered 'No (N)'	System	26 Oct 2020 18:57:22

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-10-26T13:57:20', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: '641b2b04-31f9-4041-a66e-610e915368a7' User entered '26 Oct 2020 13:57:20'	System	26 Oct 2020 18:57:22
	System	26 Oct 2020 18:57:22

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered 'Day 99'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[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 (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-11-02T10:39:15', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b10b74e2-6bc2-4d89-aa0a-4147cfeda05c'	System	02 Nov 2020 16:39:30
User entered 'No (N)'	System	02 Nov 2020 16:39:30

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

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 (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-11-02T10:39:19', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b10b74e2-6bc2-4d89-aa0a-4147cfeda05c'	System	02 Nov 2020 16:39:30
User entered 'No (N)'	System	02 Nov 2020 16:39:30

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4CFAD883-C9EF-4D5D-84AC-3EDC5073063F)', Time: '2020-11-02T10:39:27', User OID: 'PatientReportedOutcome (US3002046)', ODM File OID: 'b10b74e2-6bc2-4d89-aa0a-4147cfeda05c' User entered '02 Nov 2020 10:39:27'	System	02 Nov 2020 16:39:30
	System	02 Nov 2020 16:39:30

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 20:02:05

US3002046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 20:02:05
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 20:02:05

US3002046

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	03 Sep 2020 16:54:42
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:18:44

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:05:43
User entered 'USA-US005-2020-mRNA-1273-P301000001'	System	07 Sep 2020 17:05:11
User entered 'New'	(b) (4), (b) (6)	07 Sep 2020 17:05:11

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Broken hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 23:31:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 23:31:46
Data point term sent to Coder	System	03 Sep 2020 17:06:05
User entered 'Left Broken Hip'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'No (N)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'No (N)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '12 Aug 2020'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:24:22
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 15:39:50
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 15:39:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:39:50
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 15:39:33
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:24:22
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Nov 2020 15:39:33
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	23 Nov 2020 15:39:33
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 15:39:33
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:39:33
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Nov 2020 15:39:05
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the stop date, when available. Please do not response to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:00:38
User entered empty.	System	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User closed query 'PV query: Please provide Grade/Severity for the event.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:06:52
Query 'PV query: Please provide Grade/Severity for the event.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:03:05
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 16:02:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 16:02:35
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:02:35
User opened query 'PV query: Please provide Grade/Severity for the event.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:02:25
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 17:05:13
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[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).	(b) (4), (b) (6)	11 Nov 2020 04:55:39
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 'Pending medical records' (Site from System).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:12:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
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	04 Sep 2020 14:21:12
User entered '1'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '12 Aug 2020'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:50:45
Query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' answered with 'subject withdrew consent. Unable to obtain any records' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:55:11
User opened query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:01:44
User closed query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:28:09
Query 'PV query: Please provide the discharge date, when available.' answered with 'pending medical records' (Site from Safety).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:12:14
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User opened query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:00:04
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Sep 2020 14:21:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 14:21:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Sep 2020 17:05:13
User entered ' Aug 2020' (non-conformant).	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'No (N)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:07:00
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:03:13
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 16:02:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 16:02:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:02:35
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	07 Sep 2020 17:01:27
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 17:05:13
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 16:02:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 16:02:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:02:35
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 17:05:13
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: Per Dosing Discontinuation form IP was withdrawn due to this SAE. Please review, reconcile and update as appropriate.' answered with 'data updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:37:35
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:36:54
User opened query 'Per CDM: Per Dosing Discontinuation form IP was withdrawn due to this SAE. Please review, reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:41:12
User closed query 'Per DM CLR-RQ: Site's response noted. However, if this AE is not the reason for dosing discontinuation, then 'Investigational Product Withdrawn' is not the appropriate response for this field. Please review/reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:02:26
Query 'Per DM CLR-RQ: Site's response noted. However, if this AE is not the reason for dosing discontinuation, then 'Investigational Product Withdrawn' is not the appropriate response for this field. Please review/reconcile and update accordingly. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:34:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:34:00
User opened query 'Per DM CLR-RQ: Site's response noted. However, if this AE is not the reason for dosing discontinuation, then 'Investigational Product Withdrawn' is not the appropriate response for this field. Please review/reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 20:09:45
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 05:15:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Action taken with investigational product = Dose delayed; however the Dosing discontinuation form is completed. Please update this field as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 13:17:20
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'subject withdrew consent' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 19:19:45
Query 'Per CDM: Action taken with investigational product = Dose delayed; however the Dosing discontinuation form is completed. Please update this field as appropriate. Thank you. ' answered with 'subject withdrew consent' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:19:35
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	12 Nov 2020 19:18:58
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:18:58
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:18:58
User opened query 'Per CDM: Action taken with investigational product = Dose delayed; however the Dosing discontinuation form is completed. Please update this field as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:04:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered 'Dose Delayed (DOSE DELAYED)'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered '0'	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Medication. However, there is no Con Med recorded that matches this AE within this timeframe. Please review and add a Con Med as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 03:30:43
Query 'Per DM CLR: Other Action Taken = Medication. However, there is no Con Med recorded that matches this AE within this timeframe. Please review and add a Con Med as appropriate or update action taken.' answered with 'pending medical records' (Site from DM).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:12:24
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User opened query 'Per DM CLR: Other Action Taken = Medication. However, there is no Con Med recorded that matches this AE within this timeframe. Please review and add a Con Med as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:41:05
User entered '1'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Procedure. However, there is no Con Proc recorded that matches this AE within this timeframe. Please review and add a Con Proc as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 12:52:35
Query 'Per DM CLR: Other Action Taken = Procedure. However, there is no Con Proc recorded that matches this AE within this timeframe. Please review and add a Con Proc as appropriate or update action taken.' answered with 'pending medical records' (Site from DM).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:12:34
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User opened query 'Per DM CLR: Other Action Taken = Procedure. However, there is no Con Proc recorded that matches this AE within this timeframe. Please review and add a Con Proc as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:41:14
User entered '1'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:24:22
User closed query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:38:03
Query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' answered with 'Data updated.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:40:03
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 15:39:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:39:05
User opened query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:37:14
User closed query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:50:12
Query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' answered with 'subject withdrew consent and unable to contact' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:56:03
User opened query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:02:12
User closed query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:28:29
Query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended.' answered with 'pending medical records' (Site from Safety).	Tiffany Nemecek (b) (4) (b) (4)	09 Nov 2020 23:12:42
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:01:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:38:20
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:38:17
User closed query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:38:14
User closed query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:38:11
User closed query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:38:08
Query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' answered with 'Fall is not an AE' (Site from Safety).	Jessica Satorie (b) (4)	23 Nov 2020 23:50:05
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. Please leave query open until information is available. ' answered with 'unable to obtain records' (Site from Safety).	Jessica Satorie (b) (4)	23 Nov 2020 23:49:41
Query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' answered with 'unable to obtain records' (Site from Safety).	Jessica Satorie (b) (4)	23 Nov 2020 23:49:34
Query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' answered with 'unable to obtain records' (Site from Safety).	Jessica Satorie (b) (4)	23 Nov 2020 23:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' answered with 'unable to obtain records' (Site from Safety).	Jessica Satorie (b) (4)	23 Nov 2020 23:49:14
User opened query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:38:35
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:38:22
User opened query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:38:11
User opened query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:38:01
User opened query 'PV query: Please provide the discharge date, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:37:25
User closed query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:50:38
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:50:27
User closed query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:50:23
User closed query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:50:20

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' answered with 'subject withdrew consent and unable to contact' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:56:33
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. Please leave query open until information is available. ' answered with 'subject withdrew consent and unable to contact' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:56:28
Query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' answered with 'subject withdrew consent and unable to contact' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:56:15
Query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' answered with 'subject withdrew consent and unable to contact' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:56:08
User opened query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:04:54
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:04:44
User opened query 'PV query: Please provide laboratory/diagnostic test. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:04:35
User opened query 'PV query: Please provide the treatment medications. If none, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:04:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:28:57
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)	10 Nov 2020 18:28:46
User closed query 'PV query: Please provide laboratory/diagnostic test.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:28:39
User closed query 'PV query: Please provide the treatment medications. IF none, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:28:35
Query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so.' answered with 'pending medical records' (Site from Safety).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:13:29
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 'pending medical records' (Site from Safety).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:13:18
Query 'PV query: Please provide laboratory/diagnostic test.' answered with 'pending medical records' (Site from Safety).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:13:07
Query 'PV query: Please provide the treatment medications. IF none, please state so.' answered with 'pending medical records' (Site from Safety).	Tiffany Nemecek (b) (4)	09 Nov 2020 23:12:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:23:15
User opened query 'PV query: Please assess if "fall" met criteria for AE/SAE reporting. If so please report, if not please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 15:32:36
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)	11 Sep 2020 14:01:48
User opened query 'PV query: Please provide laboratory/diagnostic test.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:01:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the treatment medications. IF none, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 14:01:17
User entered 'Pt. was walking her dog and tripped and broke her left hip. Patient went to Bergan Mercy ER and had surgery. Medical records are pending.'	Tiffany Nemecek (b) (4)	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
User entered 'I'	System	03 Sep 2020 17:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Sep 2020 17:05:13

US3002046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Sep 2020 17:05:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:40:41

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:24:22
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:18:37

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:40:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Query 'Per CDM, CLR re-query: Other Action Taken = Procedure. However, there is no Con Procedure recorded. Please review, reconcile and update accordingly. Thank you.' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4)	24 Nov 2020 23:37:37
DataPoint Un-verified.	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	24 Nov 2020 23:36:59
User opened query 'Per CDM, CLR re-query: Other Action Taken = Procedure. However, there is no Con Procedure recorded. Please review, reconcile and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:01:47
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:24:35
User entered 'No (N)'	Tiffany Nemecek (b) (4)	03 Sep 2020 19:05:39
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:40:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Jessica Satorie (b) (4) (b) (4)	24 Nov 2020 23:37:21

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:40:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Left hip fracture repair'	Jessica Satorie (b) (4) (b) (4)	24 Nov 2020 23:37:21

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:40:41

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Jessica Satorie (b) (4) (b) (4)	24 Nov 2020 23:37:21

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:40:41

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Satorie (b) (4) (b) (4)	24 Nov 2020 23:37:21

US3002046

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:40:41

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:25:19
User entered '06 Nov 2020'	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:06

US3002046

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:40:41

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Response noted however, the reason specified for dosing discontinuation is recorded as SAE. please consider recording the primary reason for dosing discontinuation as SAE. Otherwise Clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:52:10
Query 'Per CDM re-query: Response noted however, the reason specified for dosing discontinuation is recorded as SAE. please consider recording the primary reason for dosing discontinuation as SAE. Otherwise Clarify. Thank you.' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4)	23 Nov 2020 23:52:48
DataPoint Un-verified.	Jessica Satorie (b) (4)	23 Nov 2020 23:52:41
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	23 Nov 2020 23:52:41
User opened query 'Per CDM re-query: Response noted however, the reason specified for dosing discontinuation is recorded as SAE. please consider recording the primary reason for dosing discontinuation as SAE. Otherwise Clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:13:00
User closed query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field.	(b) (4), (b) (6)	20 Nov 2020 11:09:15
' (Site from DM).		
Query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field.	(b) (4), (b) (6)	19 Nov 2020 17:35:47
' answered with 'UPDATED' (Site from DM).		

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:40:41

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:18:30
	(b) (4), (b) (6)	06 Nov 2020 20:25:21
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:06

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
Query 'Per CDM: Please note that the SAE log line number should be recorded in this field. Review and update as appropriate. ' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4)	24 Nov 2020 23:40:48
DataPoint Un-verified.	Jessica Satorie (b) (4)	24 Nov 2020 23:40:44
User entered 'PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	Jessica Satorie (b) (4)	24 Nov 2020 23:40:44
User opened query 'Per CDM: Please note that the SAE log line number should be recorded in this field. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:23:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:25:23
User entered 'PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. Medical records are still pending' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	06 Nov 2020 19:34:42
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 19:34:08
User entered 'PT. broke her hip and no longer wanted to be in the study.' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	06 Nov 2020 19:34:08
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 19:33:06
User entered empty.	Tiffany Nemecek (b) (4)	06 Nov 2020 19:33:06

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:40:41

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered '06 Nov 2020'	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:40:41

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:49:00
Query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:35:41
User opened query 'Per CDM: Per End of Study form subject discontinued due breaking her hip. Please note that there is a SAE recorded with Action taken = Investigational product withdrawn. Please review if the reason for discontinuation should be updated to to SAE. If yes, record SAE record number in the Other Specify field. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:18:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
Query 'Per CDM: Please note that the SAE log line number should be recorded in this field. Review and update as appropriate. ' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4)	24 Nov 2020 21:55:58
DataPoint Un-verified.	Jessica Satorie (b) (4)	24 Nov 2020 21:55:53
User entered 'PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. MEDICAL RECORDS ARE STILL PENDING SAEID-USA-US005-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	Jessica Satorie (b) (4)	24 Nov 2020 21:55:53
User opened query 'Per CDM: Please note that the SAE log line number should be recorded in this field. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:23:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered 'PT. BROKE HER HIP AND NO LONGER WANTED TO BE IN THE STUDY. Medical records are still pending' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	06 Nov 2020 19:34:56
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 19:34:02
User entered 'PT. broke her hip and no longer wanted to be in the study.' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	06 Nov 2020 19:34:02
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 19:33:39
User entered empty.	Tiffany Nemecek (b) (4)	06 Nov 2020 19:33:39

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:40:41

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

US3002046

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:40:41

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:40:41

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

US3002046

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:40:41

[Was autopsy performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:25:47
User entered empty.	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 19:33:39

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'USA-US005-2020-MRNA-1273-P301000001'	System	07 Sep 2020 17:05:11

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Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'USA-US005-2020-MRNA-1273-P301000001'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:40:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
User entered '07/Sep/2020 13:06'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:40:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'I'	(b) (4), (b) (6)	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'USA-US005-2020-MRNA-1273-P301000001'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:40:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
User entered '15/Sep/2020 09:07'	System	15 Sep 2020 13:07:34

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:40:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 02:12:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 13:07:34

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'USA-US005-2020-MRNA-1273-P301000001'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:40:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '13/Nov/2020 10:43'	System	13 Nov 2020 15:43:35

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:40:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 02:12:37
User entered '1' reason for change: New Information	(b) (4), (b) (6)	13 Nov 2020 15:43:35
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:02:58

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'USA-US005-2020-MRNA-1273-P301000001'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:40:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '21/Nov/2020 02:12'	System	21 Nov 2020 02:12:48

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:40:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:38:29
User entered 'I'	(b) (4), (b) (6)	21 Nov 2020 02:12:48

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'USA-US005-2020-MRNA-1273-P301000001'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'Yes (Y)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 17:06:02
User entered 'No (N)'	System	07 Sep 2020 17:05:11

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Brandon'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Essink'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '3319 N 107th'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered 'Omaha'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
Amendment Manager: User entered '68134'	System	14 Sep 2020 21:40:45

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:22:42
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:52:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:07:16
User entered 'US' (non-conformant).	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 08:40:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 14:38:40
User entered '4'	System	21 Nov 2020 02:12:48
User entered '3'	System	13 Nov 2020 15:43:35
User entered '2'	System	15 Sep 2020 13:07:34
User entered '1'	System	07 Sep 2020 17:06:08

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:40:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 14:38'	System	24 Nov 2020 14:38:40

US3002046

Folder: SAE USA-US005-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:40:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 14:38:40