

US3412125 (Prod: New Horizons Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:25:25

All time stamps listed in this document are displayed in GMT

US3412125

Form: Participant Creation

Generated On: 26 Nov 2020 09:25:25

[Participant ID](#)

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

US3412125

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	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 09:25:25

Date of Informed Consent (<i>dd MMM yyyy</i>)	04 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:25:25

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:25:25

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:25

Condition	HYPOTHYROID
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:25

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:25

Condition	IBS-O
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:25

Condition	OSTEOARTHRITIS - BACK (LOW BACK)
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:25

Condition	CHRONIC LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:25

Condition	NON ACUTE SEROUS OTITIS MEDIA (NON-INFECTIOUS) "FLUID IN EAR" (BILATERAL)
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:25

Condition	INTERMITTENT JOINT PAIN (ELBOWS / ANKLES, OCCASIONAL KNEES / HIPS)
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:25

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:25

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:35 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:35
Height (<i>xxx.x</i>)	158.0 cm
Weight (<i>xxx.x</i>)	54.7 kg
BMI (<i>xxx.x</i>)	21.91155 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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 09:25:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:25

Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Is the participant of childbearing potential?	Yes ☐
	No ☒
If No, what is the reason?	Surgically sterile ☐
	Post-menopausal ☒
	Partner medically sterile ☐
	Not reached age of Menarche ☐
	Other ☐
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2005
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

Occupational Risk

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

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
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)	True
Other	True
Specify	LIVES IN HIGH RISK COUNTY

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:25

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 184599

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 09:25:25

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 09:25:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	4 AUG 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 14:35
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 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 09:25:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	16:26 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 16:26
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:25

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	04 AUG 2020
What was the treatment time? (00:00-23:59)	15:55 (24 HR)
Treatment Date and Time (derived)	04 AUG 2020 15:55
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:25

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

04 AUG 2020

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

15:28 (24 HR)

Collection date and time (derived)

04 AUG 2020 15:28

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:25

Collection date (<i>dd MMM yyyy</i>)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:34	04 AUG 2020 15:34
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

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 09:25:25

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 16:34

PC Open Date & Time

04 AUG 2020 16:15

PC Close Date & Time

04 AUG 2020 18:45

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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 96.6 °F

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

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

PC Time Stamp	04 AUG 2020 20:09
PC Open Date & Time	04 AUG 2020 19:40
PC Close Date & Time	05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

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

95.5 °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

05 AUG 2020 19:39

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

06 AUG 2020 19:45

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 19:40

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

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

97.3 °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

08 AUG 2020 19:20

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

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

09 AUG 2020 19:06

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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 10 AUG 2020 19:01

PC Open Date & Time 10 AUG 2020 12:00

PC Close Date & Time 11 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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

04 AUG 2020 16:37

PC Open Date & Time

04 AUG 2020 16:15

PC Close Date & Time

04 AUG 2020 18:45

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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

04 AUG 2020 20:09

PC Open Date & Time

04 AUG 2020 19:40

PC Close Date & Time

05 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

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

05 AUG 2020 19:39

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

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

06 AUG 2020 19:45

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

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

07 AUG 2020 19:41

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

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

08 AUG 2020 19:20

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

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

09 AUG 2020 19:07

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

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

10 AUG 2020 19:02

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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 ☐

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 16:38
PC Open Date & Time	04 AUG 2020 16:15
PC Close Date & Time	04 AUG 2020 18:45

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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 ☐

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 20:10
PC Open Date & Time	04 AUG 2020 19:40
PC Close Date & Time	05 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	05 AUG 2020 19:40
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	06 AUG 2020 19:46
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	07 AUG 2020 19:41
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	08 AUG 2020 19:21
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	09 AUG 2020 19:07
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	10 AUG 2020 19:03
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

- 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 ☐

PC Time Stamp	11 AUG 2020 19:05
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 AUG 2020 19:05

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 12 AUG 2020 19:11

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	11 AUG 2020 19:05

PC Open Date & Time	11 AUG 2020 12:00

PC Close Date & Time	12 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	12 AUG 2020 19:12

PC Open Date & Time	12 AUG 2020 12:00

PC Close Date & Time	13 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 11 AUG 2020 19:05

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	11 AUG 2020 19:05
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	12 AUG 2020 19:12
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3412125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

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

US3412125

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412125

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412125

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 12:00
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 13:25
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3412125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	01 SEP 2020
What was the treatment time? (00:00-23:59)	12:55 (24 HR)
Treatment Date and Time (derived)	01 SEP 2020 12:55
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3412125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:25

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	01 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:08 (24 HR)
Collection date and time (derived)	01 SEP 2020 12:08

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:25

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:12	01 SEP 2020 12:12
Nasopharyngeal Swab 2	No		

US3412125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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

97.1 °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

01 SEP 2020 13:30

PC Open Date & Time

01 SEP 2020 13:15

PC Close Date & Time

01 SEP 2020 15:45

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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 97.3 °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	01 SEP 2020 19:06
PC Open Date & Time	01 SEP 2020 16:40
PC Close Date & Time	02 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

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

97.1 °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

02 SEP 2020 19:53

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 20:44

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

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	97.3 °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):

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

PC Time Stamp	04 SEP 2020 19:04
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

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

95.7 °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

05 SEP 2020 19:42

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 19:56

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 19:36

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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

01 SEP 2020 13:30

PC Open Date & Time

01 SEP 2020 13:15

PC Close Date & Time

01 SEP 2020 15:45

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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

01 SEP 2020 19:07

PC Open Date & Time

01 SEP 2020 16:40

PC Close Date & Time

02 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

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

02 SEP 2020 19:54

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

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

03 SEP 2020 20:44

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

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

04 SEP 2020 19:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

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

05 SEP 2020 19:43

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

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

06 SEP 2020 19:57

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 7

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 19:38

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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 ☐

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 13:31
PC Open Date & Time	01 SEP 2020 13:15
PC Close Date & Time	01 SEP 2020 15:45

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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 ☐

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 19:07
PC Open Date & Time	01 SEP 2020 16:40
PC Close Date & Time	02 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	02 SEP 2020 19:56
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	03 SEP 2020 20:45
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	04 SEP 2020 19:07
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	05 SEP 2020 19:44
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	06 SEP 2020 19:57
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

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 ☒

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

Yes ☐	
PC Time stamp	07 SEP 2020 19:39
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3412125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412125

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

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

US3412125

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	07 OCT 2020 18:02:36
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

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22 NOV 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

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29 NOV 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

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06 DEC 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

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17 JAN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

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24 JAN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

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03 FEB 2022 00:01

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07 FEB 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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14 FEB 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

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21 FEB 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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28 FEB 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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07 MAR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

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10 MAR 2022 00:01

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14 MAR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

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21 MAR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

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28 MAR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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04 APR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

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11 APR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

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18 APR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

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23 MAY 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

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30 MAY 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

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06 JUN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

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09 JUN 2022 00:01

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13 JUN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

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20 JUN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

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27 JUN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

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04 JUL 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

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11 JUL 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

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14 JUL 2022 00:01

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18 JUL 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3412125

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:25:25

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3412125

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:25:25

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412125

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:25:25

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	MOTOR VEHICLE ACCIDENT
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	08 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	08 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	10

v6.020 DTW (1102)

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US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

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

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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71 YOF HISTORY OF OPEN
SUBTOTAL COLECTOMY WITH
END ILEOSTOMY S/P
REVERSAL WITH LOWER
MIDLINE INCISIONAL HERNIA
S/P LAPAROSCOPIC REPAIR
WITH MESH WHO PRESENTS S/P
MVC ON SEP 8,2020 WITH
MULTIPLE INJURIES
INCLUDING SUBARACHNOID
HEMORRHAGE, BLUNT
CEREBROVASCULAR INJURY
WITH SUBSEQUENT STROKE
AND SEIZURE, GRADE IV LIVER
LACERATION, AND RIGHT
TIBIAL AND FIBULAR
FRACTURES. GIVEN HER
ANTICIPATED PROLONGED
NEED FOR VENTILATORY
SUPPORT AND ENTERAL
NUTRITION A TRACHEOSTOMY
AND PEG WERE PERFORMED.
OF NOTE, THE PATIENT ALSO
HAS AN EXTENSIVE
ABDOMINAL SURGICAL
HISTORY INCLUDING
SUBTOTAL COLECTOMY WITH
ILEORECTAL ANASTOMOSIS
AND SUBSEQUENT VENTRAL
HERNIA REPAIR WITH
PERMANENT MESH.

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

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	TRAUMATIC BRAIN INJURY
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	01 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

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

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	MULTIPLE LEFT HEMISPHERE EMBOLIC INFARCT
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	10
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	LEFT INTERCAROTID ARTERY DISSECTION WITH INTRALUMINAL THROMBUS
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	13 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

Number of Days in ICU	10
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☒
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	MOTOR VEHICLE ACCIDENT
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	CERVICAL 7 FRACTURE
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	NONDISPLACED RIB FRACTURES RIGHT 1-2
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	MRSA PNEUMONIA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	29 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	10

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	NON STEMI VS CARDIAC CONTUSION
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	13 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	01 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	10
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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	GRADE IV LIVER LACERATION
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	ACUTE POST HEMORRHAGIC ANEMIA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	08 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	10
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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

AEID

Adverse event

RIGHT TIB/ FIB FRACTURE

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐
No ☒

Start date (dd MMM yyyy)

13 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

AEID	
Adverse event	HRYPEGLYCEMUA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	13 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

AEID	
Adverse event	HYPONATREMIA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	13 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

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

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:25:25

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

Yes ☒

No ☐

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

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	AMLODIPINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

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

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	ATENOLOL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	35
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	CYCLOBENZAPRINE
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC LOW BACK PAIN
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	DICYCLOMINE HYDROCHLORIDE
Prophylaxis	Yes ☐ No ☒
Indication	IRRITABLE BOWEL SYNDROME-D
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROID
Dose per administration	75
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	LOSARTAN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	MELOXICAM
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	15
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	PSEUOBEPHEDRINE
Prophylaxis	Yes ☐ No ☒
Indication	SEROUS OTITIS MEDIA
Dose per administration	120
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	VITAMIN D
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☒ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		5 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	CALCIUM
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☒ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		5 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	OA
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	METAMUCIAL
Prophylaxis	Yes ☐ No ☒
Indication	IBS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	EIGHT OUNCE GLASS WITH SACHET
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	AMANTADINE HCL
Prophylaxis	Yes ☐ No ☒
Indication	TRAUMATIC BRAIN INJURY
Dose per administration	50/5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	PER GASTRIC TUBE	
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	
Prophylaxis	Yes ☐
	No ☐
Indication	
Dose per administration	
Dose unit	mg ☐
	ug ☐
	mL ☐
	g ☐
	IU ☐
	tablet ☐
	capsule ☐
	puff ☐
	Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐
	twice daily ☐
	three times daily ☐
	four times daily ☐
	every other day ☐
	every week ☐
	every month ☐
	as needed ☐
	once ☐
	unknown ☐
	other ☐
If frequency is Other, specify	
Route of administration	Oral ☐
	Topical ☐
	Subcutaneous ☐
	Transdermal ☐
	Intraocular ☐
	Intramuscular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:25

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

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	APIRABAN
Prophylaxis	Yes ☐ No ☒
Indication	LEFT INTERCAROTID ARTERY DISSECTION WITH INTRALUMINAL THROMBUS
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	CARVEDIOL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	3.125
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	ESOMEPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	GERD
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	PER GASTRIC TUBE	
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	FERROUS SULFATE
Prophylaxis	Yes ☐ No ☒
Indication	ANEMIA
Dose per administration	325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	INSULIN GLARGINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERGLYCEMIA
Dose per administration	20
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☒ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	INSULIN REGULAR
Prophylaxis	Yes ☐ No ☒
Indication	HYPERGLYCEMIA
Dose per administration	0-12
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☒ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☒ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	SODIUM CHLORIDE
Prophylaxis	Yes ☐ No ☒
Indication	HYPONATREMIA
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☒ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☒ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	PER NASOGASTRIC TUBE	
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	PANTAPROZOLE
Prophylaxis	Yes ☐ No ☒
Indication	GERD
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	01 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	VANCOMYCIN
Prophylaxis	Yes ☐ No ☒
Indication	MRSA PNEUMONIA
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☒ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	09 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	29 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

Name of Medication	CEFEPIME
Prophylaxis	Yes ☐ No ☒
Indication	MRSA PNEUMONIA
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☒ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	09 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	29 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:25:25

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:25:25

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 SEP 2020	TRACHESTOMY	Adverse Event	
18 SEP 2020	BRONCHOSCOPY	Adverse Event	
18 SEP 2020	PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBE PLACEMENT	Adverse Event	
13 SEP 2020	CLOSED RIGHT TIBIA-FIBULA FRACTURE	Adverse Event	
23 SEP 2020	BLOOD TRANSFUSION	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:25:25

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3412125

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:25:25

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:25

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	10/SEP/2020 12:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:25

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	22/SEP/2020 09:09
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:25:25

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	19/OCT/2020 14:07
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:25:25

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	20/OCT/2020 12:43
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:25:25

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	21/OCT/2020 13:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:25:25

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	22/OCT/2020 13:07
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:25:25

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/OCT/2020 16:05
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:25:25

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/NOV/2020 17:50
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:25:25

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	19/NOV/2020 13:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3412125 (Prod: New Horizons Clinical Research)

US3412125

Form: Participant Creation

Generated On: 26 Nov 2020 09:25:25

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3412125'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 18:29:36

US3412125

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	04 Aug 2020 19:51:37
	(b) (4)	

US3412125

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 18:29:38

US3412125

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	04 Aug 2020 19:51:37

US3412125

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	04 Aug 2020 19:51:37

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 18:29:39

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[Age](#)

Audit	User	Time (GMT)
User entered '71'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51
	(b) (4)	

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '71'	System	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51
	(b) (4)	

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[White](#)

Audit	User	Time (GMT)
User entered '1'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51
	(b) (4)	

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51
	(b) (4)	

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51
	(b) (4)	

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51
	(b) (4)	

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51
	(b) (4)	

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51
	(b) (4)	

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	04 Aug 2020 19:51:51
	(b) (4)	

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51
	(b) (4)	

US3412125

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:25

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51
	(b) (4)	

US3412125

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:25

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Steven Anderson (b) (4)	04 Aug 2020 19:52:07
	(b) (4)	

US3412125

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '2020'	System	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:25

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:07
	(b) (4)	

US3412125

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	04 Aug 2020 19:52:07
	(b) (4)	

US3412125

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 18:29:38

US3412125

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:25:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:51:37
	(b) (4)	

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:25

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:54:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:54:16
Data point term sent to Coder	System	11 Aug 2020 12:52:56
User entered 'Hypothyroid'	Steven Anderson (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '2009'	System	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:25

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:54:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:54:16
Data point term sent to Coder	System	11 Aug 2020 12:52:56
User entered 'Hypertension'	Steven Anderson (b) (4)	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:52:23
	(b) (4)	

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '2018'	System	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:25

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 07:49:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 07:49:43
Data point term sent to Coder	System	22 Oct 2020 14:03:42
Coding entries removed.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:03:24
User entered 'IBS-O' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:03:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Diarrhea predominant irritable bowel syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:06:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:06:13
Data point term sent to Coder	System	11 Aug 2020 12:52:58
User entered 'IBS-D'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:52:52
	(b) (4)	

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:25

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Spinal osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 18:28:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 18:28:42
Data point term sent to Coder	System	22 Sep 2020 12:58:11
Coding entries removed.	Melissa Fuson (b) (4)	22 Sep 2020 12:57:12
User entered 'OSTEOARTHRITIS - back (low back)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Sep 2020 12:57:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 12:55:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 12:55:08
Data point term sent to Coder	System	11 Aug 2020 12:53:59
User entered 'Osteoarthritis'	Steven Anderson (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '2014'	System	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:25

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 09:27:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 09:27:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 12:56:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 12:56:14
Data point term sent to Coder	System	11 Aug 2020 12:55:01
User entered 'Chronic Lower Back Pain'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:57:03
User entered 'un UNK 2014'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:54:01
	(b) (4)	

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	05 Nov 2020 20:57:03
User entered 'Jan 2014'	System	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '2009'	System	05 Nov 2020 20:57:03
User entered '2014'	System	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:25

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis media, LLT: Otitis media serous - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 10:05:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 10:05:08
Data point term sent to Coder	System	22 Sep 2020 12:59:12
Coding entries removed.	Melissa Fuson (b) (4)	22 Sep 2020 12:59:00
User entered 'NON ACUTE SEROUS OTITIS MEDIA (non-infectious) "fluid in ear" (bilateral)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Sep 2020 12:59:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis media acute, LLT: Otitis media acute - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 13:57:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 13:57:17
Data point term sent to Coder	System	11 Aug 2020 12:55:01
User entered 'Non acute Serous otitis media'	Steven Anderson (b) (4)	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:54:28
	(b) (4)	

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:25

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia multiple - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:04:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:04:02
Data point term sent to Coder	System	22 Sep 2020 13:01:16
User entered 'Intermittent Joint Pain (elbows / ankles, occasional knees / hips)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '2010'	System	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:25

[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)	09 Oct 2020 18:07:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	09 Oct 2020 18:07:27
Data point term sent to Coder	System	09 Oct 2020 18:06:37
User entered 'post menopausal'	Jacob sekinger (b) (4)	09 Oct 2020 18:06:22
	(b) (4)	

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Jacob sekinger (b) (4) (b) (4)	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '2005'	System	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:25

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 14:25:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 14:25:37
Data point term sent to Coder	System	22 Oct 2020 14:01:39
User entered 'GERD'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '2009'	System	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '14:35'	Steven Anderson (b) (4)	11 Aug 2020 12:56:19
	(b) (4)	

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 14:35'	System	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '158.0' cm	Steven Anderson (b) (4)	11 Aug 2020 12:56:19
DataPoint set to visible.	(b) (4) System	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '54.7' kg	Steven Anderson (b) (4)	11 Aug 2020 12:56:19
DataPoint set to visible.	(b) (4) System	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '21.91155'	System	16 Sep 2020 23:42:52
User entered '21.9'	System	11 Aug 2020 12:56:19
DataPoint set to visible.	System	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	11 Aug 2020 12:56:19
DataPoint set to visible.	System	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:48:32
User entered '36.7' C	Steven Anderson (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:48:32
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:48:32
User entered '70'	Steven Anderson (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:48:32
User entered '14'	Steven Anderson (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

[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)	21 Aug 2020 15:48:32
User entered '124'	Steven Anderson (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

[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)	21 Aug 2020 15:48:32
User entered '68'	Steven Anderson (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:56:41

US3412125

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:25

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 08:57:03
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		01 Sep 2020 16:25:11
User entered '04 Aug 2020'	Steven Anderson (b) (4)	11 Aug 2020 12:56:41
	(b) (4)	

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:25

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:25

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)	21 Oct 2020 06:05:59
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 'updated. ' (Site from DM).	Jacob sekinger (b) (4)	09 Oct 2020 18:07:49
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)	08 Oct 2020 05:05:05
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:25

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:25

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '1'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

[Other](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Sep 2020 13:14:38
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:25

[Specify](#)

Audit	User	Time (GMT)
User entered 'Lives in High Risk County' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Sep 2020 13:14:38
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:28
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Steven Anderson (b) (4) (b) (4)	04 Aug 2020 19:52:28

US3412125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	04 Aug 2020 19:52:28

US3412125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	04 Aug 2020 19:52:28

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 19:44:26

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:25

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 02:02:25
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:02:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 19:44:26
User entered '184599' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:44:26

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 19:44:26

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:25

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)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:41
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:41
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	04 Aug 2020 19:52:41

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:25

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:41
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:25

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:41
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:25

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:25

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:25

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:25

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:35' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '4 Aug 2020 14:35'	System	21 Aug 2020 15:50:24
User entered empty.	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 15:50:24
User entered empty.	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 15:50:24
User entered empty.	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 15:50:24
User entered empty.	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '68' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 15:50:24
User entered empty.	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:25

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:25

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[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)	17 Aug 2020 17:50:45
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 12:59:27
User entered '16:26'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:26'	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.4' F	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

Pulse (xxx)

Audit	User	Time (GMT)
User entered '68'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '14'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 19:01:30
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 15:51:01
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 12:59:27
User entered '158'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '72'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 13:00:12

US3412125

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 13:00:12

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	04 Aug 2020 20:00:44
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	04 Aug 2020 20:00:44
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	04 Aug 2020 20:00:44
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Steven Anderson (b) (4)	04 Aug 2020 20:00:44
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '15:55'	Steven Anderson (b) (4)	04 Aug 2020 20:00:44
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:55'	System	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	04 Aug 2020 20:00:44
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 13:02:11
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 13:02:11

US3412125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '15:28'	Steven Anderson (b) (4)	11 Aug 2020 13:02:11
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:28'	System	11 Aug 2020 13:02:11

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:25

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '15:34'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:34'	System	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:25

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 13:03:28
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 13:03:28

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:33:59', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4fc55baa-c5b5-435d-8798-3af5a9634053'	System	04 Aug 2020 20:34:59
User entered 'Yes (Y)'	System	04 Aug 2020 20:34:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:34:14', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4fc55baa-c5b5-435d-8798-3af5a9634053'	System	04 Aug 2020 20:34:59
User entered '97.4'	System	04 Aug 2020 20:34:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:34:34', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4fc55baa-c5b5-435d-8798-3af5a9634053'	System	04 Aug 2020 20:34:59
User entered 'No (N)'	System	04 Aug 2020 20:34:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:34:54', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4fc55baa-c5b5-435d-8798-3af5a9634053'	System	04 Aug 2020 20:34:59
User entered '04 Aug 2020 16:34'	System	04 Aug 2020 20:34:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:15'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 18:45'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:08:44', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'db819a99-2cb1-4766-bee9-0250ceefe29a'	System	05 Aug 2020 00:09:20
User entered 'Yes (Y)'	System	05 Aug 2020 00:09:20

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'db819a99-2cb1-4766-bee9-0250ceefe29a'	System	05 Aug 2020 00:09:20
User entered '96.6'	System	05 Aug 2020 00:09:20

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:06', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'db819a99-2cb1-4766-bee9-0250ceefe29a'	System	05 Aug 2020 00:09:20
User entered 'No (N)'	System	05 Aug 2020 00:09:20

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'db819a99-2cb1-4766-bee9-0250ceefe29a'	System	05 Aug 2020 00:09:20
User entered '04 Aug 2020 20:09'	System	05 Aug 2020 00:09:20

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:40'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 2'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:38:30', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'b88e7c59-3960-47ee-baac-182065971304'	System	05 Aug 2020 23:39:02
User entered 'Yes (Y)'	System	05 Aug 2020 23:39:02

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:38:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'b88e7c59-3960-47ee-baac-182065971304'	System	05 Aug 2020 23:39:02
User entered '95.5'	System	05 Aug 2020 23:39:02

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:38:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'b88e7c59-3960-47ee-baac-182065971304'	System	05 Aug 2020 23:39:02
User entered 'No (N)'	System	05 Aug 2020 23:39:02

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'b88e7c59-3960-47ee-baac-182065971304'	System	05 Aug 2020 23:39:02
User entered '05 Aug 2020 19:39'	System	05 Aug 2020 23:39:02

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 3'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:44:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '60db8904-c049-48c1-82bf-87ff24e101b6'	System	06 Aug 2020 23:45:09
User entered 'Yes (Y)'	System	06 Aug 2020 23:45:09

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:44:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '60db8904-c049-48c1-82bf-87ff24e101b6'	System	06 Aug 2020 23:45:09
User entered '97.5'	System	06 Aug 2020 23:45:09

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '60db8904-c049-48c1-82bf-87ff24e101b6'	System	06 Aug 2020 23:45:09
User entered 'No (N)'	System	06 Aug 2020 23:45:09

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '60db8904-c049-48c1-82bf-87ff24e101b6'	System	06 Aug 2020 23:45:09
User entered '06 Aug 2020 19:45'	System	06 Aug 2020 23:45:09

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 4'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:39:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6c2135cf-c68a-46eb-9006-814c75841018'	System	07 Aug 2020 23:40:21
User entered 'Yes (Y)'	System	07 Aug 2020 23:40:21

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:39:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6c2135cf-c68a-46eb-9006-814c75841018'	System	07 Aug 2020 23:40:21
User entered '97.6'	System	07 Aug 2020 23:40:21

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6c2135cf-c68a-46eb-9006-814c75841018'	System	07 Aug 2020 23:40:21
User entered 'No (N)'	System	07 Aug 2020 23:40:21

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:20', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6c2135cf-c68a-46eb-9006-814c75841018'	System	07 Aug 2020 23:40:21
User entered '07 Aug 2020 19:40'	System	07 Aug 2020 23:40:21

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 5'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:19:47', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0456073f-e015-4cc1-bc1e-cdc777ec8825'	System	08 Aug 2020 23:20:16
User entered 'Yes (Y)'	System	08 Aug 2020 23:20:16

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:04', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0456073f-e015-4cc1-bc1e-cdc777ec8825'	System	08 Aug 2020 23:20:16
User entered '97.3'	System	08 Aug 2020 23:20:16

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:07', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0456073f-e015-4cc1-bc1e-cdc777ec8825'	System	08 Aug 2020 23:20:16
User entered 'No (N)'	System	08 Aug 2020 23:20:16

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:12', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0456073f-e015-4cc1-bc1e-cdc777ec8825'	System	08 Aug 2020 23:20:16
User entered '08 Aug 2020 19:20'	System	08 Aug 2020 23:20:16

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 6'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:06:34', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '8fd165fe-cf42-42e1-9861-a01d1e6efbb2'	System	09 Aug 2020 23:06:56
User entered 'Yes (Y)'	System	09 Aug 2020 23:06:56

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:06:41', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '8fd165fe-cf42-42e1-9861-a01d1e6efbb2'	System	09 Aug 2020 23:06:56
User entered '98.1'	System	09 Aug 2020 23:06:56

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:06:45', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '8fd165fe-cf42-42e1-9861-a01d1e6efbb2'	System	09 Aug 2020 23:06:56
User entered 'No (N)'	System	09 Aug 2020 23:06:56

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:06:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '8fd165fe-cf42-42e1-9861-a01d1e6efbb2'	System	09 Aug 2020 23:06:56
User entered '09 Aug 2020 19:06'	System	09 Aug 2020 23:06:56

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 7'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:01:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '22920d55-0293-48f0-a960-2380041e319a'	System	10 Aug 2020 23:01:44
User entered 'Yes (Y)'	System	10 Aug 2020 23:01:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:01:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '22920d55-0293-48f0-a960-2380041e319a'	System	10 Aug 2020 23:01:44
User entered '98.3'	System	10 Aug 2020 23:01:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:01:35', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '22920d55-0293-48f0-a960-2380041e319a'	System	10 Aug 2020 23:01:44
User entered 'No (N)'	System	10 Aug 2020 23:01:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:01:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '22920d55-0293-48f0-a960-2380041e319a'	System	10 Aug 2020 23:01:44
User entered '10 Aug 2020 19:01'	System	10 Aug 2020 23:01:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:36:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '296a5857-6b5c-418b-b1a1-e48d575f772a'	System	04 Aug 2020 20:37:22
User entered 'None (1)'	System	04 Aug 2020 20:37:22

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:36:55', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '296a5857-6b5c-418b-b1a1-e48d575f772a'	System	04 Aug 2020 20:37:22
User entered 'No (N)'	System	04 Aug 2020 20:37:22

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:36:59', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '296a5857-6b5c-418b-b1a1-e48d575f772a'	System	04 Aug 2020 20:37:22
User entered 'No (N)'	System	04 Aug 2020 20:37:22

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:37:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '296a5857-6b5c-418b-b1a1-e48d575f772a'	System	04 Aug 2020 20:37:22
User entered 'None (1)'	System	04 Aug 2020 20:37:22

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:37:20', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '296a5857-6b5c-418b-b1a1-e48d575f772a'	System	04 Aug 2020 20:37:22
User entered '04 Aug 2020 16:37'	System	04 Aug 2020 20:37:22

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:15'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 18:45'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:29', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '47189bde-c23e-4a46-bbf7-87f20aba16cc'	System	05 Aug 2020 00:09:51
User entered 'None (1)'	System	05 Aug 2020 00:09:51

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:32', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '47189bde-c23e-4a46-bbf7-87f20aba16cc'	System	05 Aug 2020 00:09:51
User entered 'No (N)'	System	05 Aug 2020 00:09:51

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:35', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '47189bde-c23e-4a46-bbf7-87f20aba16cc'	System	05 Aug 2020 00:09:51
User entered 'No (N)'	System	05 Aug 2020 00:09:51

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:39', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '47189bde-c23e-4a46-bbf7-87f20aba16cc'	System	05 Aug 2020 00:09:51
User entered 'None (1)'	System	05 Aug 2020 00:09:51

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:48', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '47189bde-c23e-4a46-bbf7-87f20aba16cc'	System	05 Aug 2020 00:09:51
User entered '04 Aug 2020 20:09'	System	05 Aug 2020 00:09:51

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:40'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 2'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

[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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:07', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a387c581-a668-4faa-8400-3056073c5b52'	System	05 Aug 2020 23:39:28
User entered 'None (1)'	System	05 Aug 2020 23:39:28

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:11', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a387c581-a668-4faa-8400-3056073c5b52'	System	05 Aug 2020 23:39:28
User entered 'No (N)'	System	05 Aug 2020 23:39:28

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:14', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a387c581-a668-4faa-8400-3056073c5b52'	System	05 Aug 2020 23:39:28
User entered 'No (N)'	System	05 Aug 2020 23:39:28

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a387c581-a668-4faa-8400-3056073c5b52'	System	05 Aug 2020 23:39:28
User entered 'None (1)'	System	05 Aug 2020 23:39:28

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:27', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a387c581-a668-4faa-8400-3056073c5b52'	System	05 Aug 2020 23:39:28
User entered '05 Aug 2020 19:39'	System	05 Aug 2020 23:39:28

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 3'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

[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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:19', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '48346898-1727-4798-a44c-0a3e5625fc8d'	System	06 Aug 2020 23:45:40
User entered 'None (1)'	System	06 Aug 2020 23:45:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '48346898-1727-4798-a44c-0a3e5625fc8d'	System	06 Aug 2020 23:45:40
User entered 'No (N)'	System	06 Aug 2020 23:45:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:26', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '48346898-1727-4798-a44c-0a3e5625fc8d'	System	06 Aug 2020 23:45:40
User entered 'No (N)'	System	06 Aug 2020 23:45:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:30', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '48346898-1727-4798-a44c-0a3e5625fc8d'	System	06 Aug 2020 23:45:40
User entered 'None (1)'	System	06 Aug 2020 23:45:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '48346898-1727-4798-a44c-0a3e5625fc8d'	System	06 Aug 2020 23:45:40
User entered '06 Aug 2020 19:45'	System	06 Aug 2020 23:45:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 4'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:37', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a34bc3d-a33e-45b8-80d7-330d06ae6a54'	System	07 Aug 2020 23:41:05
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 23:41:05

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:40', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a34bc3d-a33e-45b8-80d7-330d06ae6a54'	System	07 Aug 2020 23:41:05
User entered 'No (N)'	System	07 Aug 2020 23:41:05

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:44', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a34bc3d-a33e-45b8-80d7-330d06ae6a54'	System	07 Aug 2020 23:41:05
User entered 'No (N)'	System	07 Aug 2020 23:41:05

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:47', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a34bc3d-a33e-45b8-80d7-330d06ae6a54'	System	07 Aug 2020 23:41:05
User entered 'None (1)'	System	07 Aug 2020 23:41:05

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a34bc3d-a33e-45b8-80d7-330d06ae6a54'	System	07 Aug 2020 23:41:05
User entered '07 Aug 2020 19:41'	System	07 Aug 2020 23:41:05

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 5'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:21', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '57fbf54d-b25f-4f0a-81f0-1930a78e45d8'	System	08 Aug 2020 23:20:40
User entered 'None (1)'	System	08 Aug 2020 23:20:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:24', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '57fbf54d-b25f-4f0a-81f0-1930a78e45d8'	System	08 Aug 2020 23:20:40
User entered 'No (N)'	System	08 Aug 2020 23:20:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:27', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '57fbf54d-b25f-4f0a-81f0-1930a78e45d8'	System	08 Aug 2020 23:20:40
User entered 'No (N)'	System	08 Aug 2020 23:20:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '57fbf54d-b25f-4f0a-81f0-1930a78e45d8'	System	08 Aug 2020 23:20:40
User entered 'None (1)'	System	08 Aug 2020 23:20:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '57fbf54d-b25f-4f0a-81f0-1930a78e45d8'	System	08 Aug 2020 23:20:40
User entered '08 Aug 2020 19:20'	System	08 Aug 2020 23:20:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 6'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '2f0f9914-17a0-465e-8c72-c89320f92ef9'	System	09 Aug 2020 23:07:23
User entered 'None (1)'	System	09 Aug 2020 23:07:23

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '2f0f9914-17a0-465e-8c72-c89320f92ef9'	System	09 Aug 2020 23:07:23
User entered 'No (N)'	System	09 Aug 2020 23:07:23

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:11', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '2f0f9914-17a0-465e-8c72-c89320f92ef9'	System	09 Aug 2020 23:07:23
User entered 'No (N)'	System	09 Aug 2020 23:07:23

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:15', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '2f0f9914-17a0-465e-8c72-c89320f92ef9'	System	09 Aug 2020 23:07:23
User entered 'None (1)'	System	09 Aug 2020 23:07:23

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '2f0f9914-17a0-465e-8c72-c89320f92ef9'	System	09 Aug 2020 23:07:23
User entered '09 Aug 2020 19:07'	System	09 Aug 2020 23:07:23

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 7'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'be9ceade-3cf2-41ce-9471-1866cdb1dd70'	System	10 Aug 2020 23:02:37
User entered 'None (1)'	System	10 Aug 2020 23:02:37

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:07', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'be9ceade-3cf2-41ce-9471-1866cdb1dd70'	System	10 Aug 2020 23:02:37
User entered 'No (N)'	System	10 Aug 2020 23:02:37

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'be9ceade-3cf2-41ce-9471-1866cdb1dd70'	System	10 Aug 2020 23:02:37
User entered 'No (N)'	System	10 Aug 2020 23:02:37

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'be9ceade-3cf2-41ce-9471-1866cdb1dd70'	System	10 Aug 2020 23:02:37
User entered 'None (1)'	System	10 Aug 2020 23:02:37

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'be9ceade-3cf2-41ce-9471-1866cdb1dd70'	System	10 Aug 2020 23:02:37
User entered '10 Aug 2020 19:02'	System	10 Aug 2020 23:02:37

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:00', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:06', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:14', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:21', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:26', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:37', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'No (N)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:56', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered '04 Aug 2020 16:38'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:15'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 18:45'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:55', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca'	System	05 Aug 2020 00:10:30
User entered 'None (0)'	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca'	System	05 Aug 2020 00:10:30
User entered 'None (0)'	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca'	System	05 Aug 2020 00:10:30
User entered 'None (0)'	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca' User entered 'None (0)'	System	05 Aug 2020 00:10:30
	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca'	System	05 Aug 2020 00:10:30
User entered 'None (0)'	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:10', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca'	System	05 Aug 2020 00:10:30
User entered 'None (0)'	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:17', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca'	System	05 Aug 2020 00:10:30
User entered 'No (N)'	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca'	System	05 Aug 2020 00:10:30
User entered '04 Aug 2020 20:10'	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:40'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 2'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'None (0)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:34', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'None (0)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'None (0)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'None (0)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:48', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'None (0)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'None (0)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:56', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'No (N)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:40:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered '05 Aug 2020 19:40'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 3'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered 'None (0)'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:46', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149' User entered 'None (0)'	System	06 Aug 2020 23:46:20
	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered 'No interference with activity (1)'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered 'No interference with activity (1)'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:46:00', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered 'None (0)'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:46:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered 'None (0)'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:46:09', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered 'No (N)'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:46:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered '06 Aug 2020 19:46'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 4'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:09', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f'	System	07 Aug 2020 23:41:55
User entered 'None (0)'	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:16', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f'	System	07 Aug 2020 23:41:55
User entered 'No interference with activity (1)'	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:24', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f'	System	07 Aug 2020 23:41:55
User entered 'No interference with activity (1)'	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f'	System	07 Aug 2020 23:41:55
User entered 'No interference with activity (1)'	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f'	System	07 Aug 2020 23:41:55
User entered 'None (0)'	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:40', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f'	System	07 Aug 2020 23:41:55
User entered 'None (0)'	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:44', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f'	System	07 Aug 2020 23:41:55
User entered 'No (N)'	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f' User entered '07 Aug 2020 19:41'	System	07 Aug 2020 23:41:55
	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 5'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa'	System	08 Aug 2020 23:21:11
User entered 'None (0)'	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:46', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa'	System	08 Aug 2020 23:21:11
User entered 'None (0)'	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa'	System	08 Aug 2020 23:21:11
User entered 'No interference with activity (1)'	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:52', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa'	System	08 Aug 2020 23:21:11
User entered 'No interference with activity (1)'	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:55', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa'	System	08 Aug 2020 23:21:11
User entered 'None (0)'	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa'	System	08 Aug 2020 23:21:11
User entered 'None (0)'	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:21:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa'	System	08 Aug 2020 23:21:11
User entered 'No (N)'	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:21:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa'	System	08 Aug 2020 23:21:11
User entered '08 Aug 2020 19:21'	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 6'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:30', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a'	System	09 Aug 2020 23:08:00
User entered 'None (0)'	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a'	System	09 Aug 2020 23:08:00
User entered 'None (0)'	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a'	System	09 Aug 2020 23:08:00
User entered 'None (0)'	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a' User entered 'None (0)'	System	09 Aug 2020 23:08:00
	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:45', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a'	System	09 Aug 2020 23:08:00
User entered 'None (0)'	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:48', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a' User entered 'None (0)'	System	09 Aug 2020 23:08:00
	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:52', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a'	System	09 Aug 2020 23:08:00
User entered 'No (N)'	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a'	System	09 Aug 2020 23:08:00
User entered '09 Aug 2020 19:07'	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 7'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:40', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc' User entered 'None (0)'	System	10 Aug 2020 23:03:54
	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:21', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered 'None (0)'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered 'No (N)'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc' User entered '10 Aug 2020 19:03'	System	10 Aug 2020 23:03:54
	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 8'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:25:25

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:20', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '581af6fe-378f-449f-a1c0-9d2e39227fe7'	System	11 Aug 2020 23:05:28
User entered 'None (0)'	System	11 Aug 2020 23:05:28

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '581af6fe-378f-449f-a1c0-9d2e39227fe7'	System	11 Aug 2020 23:05:28
User entered '11 Aug 2020 19:05'	System	11 Aug 2020 23:05:28

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 8'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a99396d-920f-447e-9cb8-92b997d811f9'	System	11 Aug 2020 23:05:15
User entered 'No interference with activity (1)'	System	11 Aug 2020 23:05:15

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a99396d-920f-447e-9cb8-92b997d811f9'	System	11 Aug 2020 23:05:15
User entered '11 Aug 2020 19:05'	System	11 Aug 2020 23:05:15

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 9'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:11:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd641430a-dfdc-4b5e-b84a-356bf66a7fd8'	System	12 Aug 2020 23:11:59
User entered 'None (0)'	System	12 Aug 2020 23:11:59

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:11:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd641430a-dfdc-4b5e-b84a-356bf66a7fd8'	System	12 Aug 2020 23:11:59
User entered '12 Aug 2020 19:11'	System	12 Aug 2020 23:11:59

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 8'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9dc84981-3a75-474b-bdd8-60853a462b32'	System	11 Aug 2020 23:05:40
User entered 'No interference with activity (1)'	System	11 Aug 2020 23:05:40

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9dc84981-3a75-474b-bdd8-60853a462b32'	System	11 Aug 2020 23:05:40
User entered '11 Aug 2020 19:05'	System	11 Aug 2020 23:05:40

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 9'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:12:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '7974bd17-75cc-450c-93a9-83f7bbc9ae2c'	System	12 Aug 2020 23:12:10
User entered 'None (0)'	System	12 Aug 2020 23:12:10

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:12:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '7974bd17-75cc-450c-93a9-83f7bbc9ae2c'	System	12 Aug 2020 23:12:10
User entered '12 Aug 2020 19:12'	System	12 Aug 2020 23:12:10

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 8'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:25:25

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'eb55d0c4-d181-4429-be96-35c922f1f804'	System	11 Aug 2020 23:05:50
User entered 'None (0)'	System	11 Aug 2020 23:05:50

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'eb55d0c4-d181-4429-be96-35c922f1f804'	System	11 Aug 2020 23:05:50
User entered '11 Aug 2020 19:05'	System	11 Aug 2020 23:05:50

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 8'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:54', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '7c595b39-3d16-4959-8d24-a4548f0d9c20'	System	11 Aug 2020 23:06:01
User entered 'No (N)'	System	11 Aug 2020 23:06:01

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '7c595b39-3d16-4959-8d24-a4548f0d9c20'	System	11 Aug 2020 23:06:01
User entered '11 Aug 2020 19:05'	System	11 Aug 2020 23:06:01

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 9'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:12:15', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6e4d40ff-34b1-40ed-aba5-bbb0c8486cce'	System	12 Aug 2020 23:12:21
User entered 'No (N)'	System	12 Aug 2020 23:12:21

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:12:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6e4d40ff-34b1-40ed-aba5-bbb0c8486cce'	System	12 Aug 2020 23:12:21
User entered '12 Aug 2020 19:12'	System	12 Aug 2020 23:12:21

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	12 Aug 2020 20:03:51
	(b) (4)	

US3412125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Steven Anderson (b) (4) (b) (4)	12 Aug 2020 20:03:51

US3412125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	12 Aug 2020 20:03:51
	(b) (4)	

US3412125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	12 Aug 2020 20:03:51

US3412125

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	12 Aug 2020 20:04:32

US3412125

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:04:32

US3412125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:07:08
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Aug 2020 23:14:29

US3412125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:07:08
User entered '19 Aug 2020'	Steven Anderson (b) (4)	19 Aug 2020 23:14:29

US3412125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:07:08
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	19 Aug 2020 23:14:29

US3412125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:07:08
User entered empty.	Steven Anderson (b) (4)	19 Aug 2020 23:14:29

US3412125

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:06:47
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Aug 2020 23:14:34

US3412125

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 23:14:34

US3412125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:23:10
	(b) (4)	

US3412125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Steven Anderson (b) (4) (b) (4)	01 Sep 2020 16:23:10

US3412125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	01 Sep 2020 16:23:10

US3412125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:23:10
	(b) (4)	

US3412125

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:23:15
	(b) (4)	

US3412125

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:23:15

US3412125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:25:11
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Steven Anderson (b) (4) (b) (4)	01 Sep 2020 16:25:11

US3412125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	01 Sep 2020 16:25:11

US3412125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	01 Sep 2020 16:25:11

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Steven Anderson (b) (4) (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '12:00'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '16'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '110'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '64'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 18:52:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 18:52:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 16:26:12
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '13:25' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:25'	System	16 Sep 2020 18:52:43
User entered empty.	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '97.1' F reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 18:52:43
User entered empty.	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '12' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 18:52:43
User entered empty.	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '130' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 18:52:43
User entered empty.	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '68' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 18:52:43
User entered empty.	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	01 Sep 2020 16:26:31

US3412125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Steven Anderson (b) (4) (b) (4)	01 Sep 2020 16:26:31

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:42:41
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:42:41
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Steven Anderson (b) (4)	01 Sep 2020 16:42:41
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '12:55'	Steven Anderson (b) (4)	01 Sep 2020 16:42:41
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:55'	System	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	01 Sep 2020 16:42:41
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:27:32
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Steven Anderson (b) (4)	01 Sep 2020 16:27:32
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '12:08'	Steven Anderson (b) (4)	01 Sep 2020 16:27:32
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:08'	System	01 Sep 2020 16:27:32

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Steven Anderson (b) (4)	01 Sep 2020 16:27:52
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:25

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:27:52
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '12:12'	Steven Anderson (b) (4)	01 Sep 2020 16:27:52
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:12'	System	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:25

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:27:52
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	01 Sep 2020 16:27:58

US3412125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:27:58

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:29:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '004b445d-8163-45bb-8b7a-d033f9ca6be9'	System	01 Sep 2020 17:30:17
User entered 'Yes (Y)'	System	01 Sep 2020 17:30:17

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:29:41', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '004b445d-8163-45bb-8b7a-d033f9ca6be9'	System	01 Sep 2020 17:30:17
User entered '97.1'	System	01 Sep 2020 17:30:17

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '004b445d-8163-45bb-8b7a-d033f9ca6be9'	System	01 Sep 2020 17:30:17
User entered 'No (N)'	System	01 Sep 2020 17:30:17

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '004b445d-8163-45bb-8b7a-d033f9ca6be9'	System	01 Sep 2020 17:30:17
User entered '01 Sep 2020 13:30'	System	01 Sep 2020 17:30:17

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:15'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:45'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:15', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '3ca70747-a2d3-4e8f-90e1-a72d5a5fe5af'	System	01 Sep 2020 23:06:40
User entered 'Yes (Y)'	System	01 Sep 2020 23:06:40

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '3ca70747-a2d3-4e8f-90e1-a72d5a5fe5af' User entered '97.3'	System	01 Sep 2020 23:06:40

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:30', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '3ca70747-a2d3-4e8f-90e1-a72d5a5fe5af'	System	01 Sep 2020 23:06:40
User entered 'No (N)'	System	01 Sep 2020 23:06:40

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '3ca70747-a2d3-4e8f-90e1-a72d5a5fe5af'	System	01 Sep 2020 23:06:40
User entered '01 Sep 2020 19:06'	System	01 Sep 2020 23:06:40

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 16:40'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 2'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '37de59e5-b47e-4a17-b1e5-5b7bbec5d42b'	System	02 Sep 2020 23:53:32
User entered 'Yes (Y)'	System	02 Sep 2020 23:53:32

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '37de59e5-b47e-4a17-b1e5-5b7bbec5d42b' User entered '97.1'	System	02 Sep 2020 23:53:32
	System	02 Sep 2020 23:53:32

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:17', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '37de59e5-b47e-4a17-b1e5-5b7bbec5d42b'	System	02 Sep 2020 23:53:32
User entered 'No (N)'	System	02 Sep 2020 23:53:32

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '37de59e5-b47e-4a17-b1e5-5b7bbec5d42b'	System	02 Sep 2020 23:53:32
User entered '02 Sep 2020 19:53'	System	02 Sep 2020 23:53:32

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 3'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:43:50', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '11800d38-e4ae-4a40-a555-873941348ab6'	System	04 Sep 2020 00:44:11
User entered 'Yes (Y)'	System	04 Sep 2020 00:44:11

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:43:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '11800d38-e4ae-4a40-a555-873941348ab6'	System	04 Sep 2020 00:44:11
User entered '96.8'	System	04 Sep 2020 00:44:11

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '11800d38-e4ae-4a40-a555-873941348ab6'	System	04 Sep 2020 00:44:11
User entered 'No (N)'	System	04 Sep 2020 00:44:11

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:09', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '11800d38-e4ae-4a40-a555-873941348ab6'	System	04 Sep 2020 00:44:11
User entered '03 Sep 2020 20:44'	System	04 Sep 2020 00:44:11

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 4'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:02:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796'	System	04 Sep 2020 23:04:09
User entered 'Yes (Y)'	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:03:27', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796'	System	04 Sep 2020 23:04:09
User entered '97.3'	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:03:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796'	System	04 Sep 2020 23:04:09
User entered 'Yes (Y)'	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACTED' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 10:00:39
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:03:52', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796'	Mylene Asmar-Rios (b) (4)	02 Oct 2020 17:15:52
User entered '1'	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:03:52', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796'	System	04 Sep 2020 23:04:09
User entered '0'	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:04:06', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796'	System	04 Sep 2020 23:04:09
User entered '04 Sep 2020 19:04'	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 5'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:42:20', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd2b1c41d-b82a-4d81-a0ea-eccde9726715'	System	05 Sep 2020 23:42:44
User entered 'Yes (Y)'	System	05 Sep 2020 23:42:44

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:42:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd2b1c41d-b82a-4d81-a0ea-eccde9726715'	System	05 Sep 2020 23:42:44
User entered '95.7'	System	05 Sep 2020 23:42:44

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:42:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd2b1c41d-b82a-4d81-a0ea-eccde9726715'	System	05 Sep 2020 23:42:44
User entered 'No (N)'	System	05 Sep 2020 23:42:44

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:42:42', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd2b1c41d-b82a-4d81-a0ea-eccde9726715'	System	05 Sep 2020 23:42:44
User entered '05 Sep 2020 19:42'	System	05 Sep 2020 23:42:44

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 6'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:55:52', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd430823e-ddd0-4ee0-bf03-ffaf9eff6e0f'	System	06 Sep 2020 23:56:10
User entered 'Yes (Y)'	System	06 Sep 2020 23:56:10

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:55:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd430823e-ddd0-4ee0-bf03-ffaf9eff6e0f' User entered '97.0'	System	06 Sep 2020 23:56:10

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd430823e-ddd0-4ee0-bf03-ffaf9eff6e0f'	System	06 Sep 2020 23:56:10
User entered 'No (N)'	System	06 Sep 2020 23:56:10

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd430823e-ddd0-4ee0-bf03-ffaf9eff6e0f'	System	06 Sep 2020 23:56:10
User entered '06 Sep 2020 19:56'	System	06 Sep 2020 23:56:10

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 7'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:35:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f18ab851-292c-4d86-92e1-701ae1a1204b'	System	07 Sep 2020 23:36:27
User entered 'Yes (Y)'	System	07 Sep 2020 23:36:27

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:36:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f18ab851-292c-4d86-92e1-701ae1a1204b'	System	07 Sep 2020 23:36:27
User entered '98.0'	System	07 Sep 2020 23:36:27

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:36:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f18ab851-292c-4d86-92e1-701ae1a1204b'	System	07 Sep 2020 23:36:27
User entered 'No (N)'	System	07 Sep 2020 23:36:27

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:36:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f18ab851-292c-4d86-92e1-701ae1a1204b'	System	07 Sep 2020 23:36:27
User entered '07 Sep 2020 19:36'	System	07 Sep 2020 23:36:27

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:26', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f0f3024b-72fb-450d-acc4-1c2627ad1b38'	System	01 Sep 2020 17:30:56
User entered 'Any use of prescription pain reliever or prevents daily activity (4)'	System	01 Sep 2020 17:30:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:30', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f0f3024b-72fb-450d-acc4-1c2627ad1b38'	System	01 Sep 2020 17:30:56
User entered 'No (N)'	System	01 Sep 2020 17:30:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f0f3024b-72fb-450d-acc4-1c2627ad1b38'	System	01 Sep 2020 17:30:56
User entered 'No (N)'	System	01 Sep 2020 17:30:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:39', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f0f3024b-72fb-450d-acc4-1c2627ad1b38'	System	01 Sep 2020 17:30:56
User entered 'None (1)'	System	01 Sep 2020 17:30:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f0f3024b-72fb-450d-acc4-1c2627ad1b38'	System	01 Sep 2020 17:30:56
User entered '01 Sep 2020 13:30'	System	01 Sep 2020 17:30:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:15'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:45'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'ba0719bb-ab44-4aba-8a57-642cbef4fed5'	System	01 Sep 2020 23:07:18
User entered 'None (1)'	System	01 Sep 2020 23:07:18

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'ba0719bb-ab44-4aba-8a57-642cbef4fed5'	System	01 Sep 2020 23:07:18
User entered 'No (N)'	System	01 Sep 2020 23:07:18

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'ba0719bb-ab44-4aba-8a57-642cbef4fed5'	System	01 Sep 2020 23:07:18
User entered 'No (N)'	System	01 Sep 2020 23:07:18

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:04', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'ba0719bb-ab44-4aba-8a57-642cbef4fed5'	System	01 Sep 2020 23:07:18
User entered 'None (1)'	System	01 Sep 2020 23:07:18

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:16', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'ba0719bb-ab44-4aba-8a57-642cbef4fed5'	System	01 Sep 2020 23:07:18
User entered '01 Sep 2020 19:07'	System	01 Sep 2020 23:07:18

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 16:40'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 2'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:55', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '79c5cb8f-985a-4b6e-8fff-e1d7a785deca'	System	02 Sep 2020 23:54:30
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	02 Sep 2020 23:54:30

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:59', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '79c5cb8f-985a-4b6e-8fff-e1d7a785deca'	System	02 Sep 2020 23:54:30
User entered 'No (N)'	System	02 Sep 2020 23:54:30

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '79c5cb8f-985a-4b6e-8fff-e1d7a785deca'	System	02 Sep 2020 23:54:30
User entered 'No (N)'	System	02 Sep 2020 23:54:30

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:10', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '79c5cb8f-985a-4b6e-8fff-e1d7a785deca' User entered 'None (1)'	System	02 Sep 2020 23:54:30
	System	02 Sep 2020 23:54:30

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '79c5cb8f-985a-4b6e-8fff-e1d7a785deca'	System	02 Sep 2020 23:54:30
User entered '02 Sep 2020 19:54'	System	02 Sep 2020 23:54:30

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 3'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

[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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:21', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9d8b5ef2-ae2f-4804-aab0-e061f231972c' User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 00:44:49
	System	04 Sep 2020 00:44:49

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:24', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9d8b5ef2-ae2f-4804-aab0-e061f231972c'	System	04 Sep 2020 00:44:49
User entered 'No (N)'	System	04 Sep 2020 00:44:49

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9d8b5ef2-ae2f-4804-aab0-e061f231972c'	System	04 Sep 2020 00:44:49
User entered 'No (N)'	System	04 Sep 2020 00:44:49

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:35', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9d8b5ef2-ae2f-4804-aab0-e061f231972c' User entered 'None (1)'	System	04 Sep 2020 00:44:49

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:46', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9d8b5ef2-ae2f-4804-aab0-e061f231972c'	System	04 Sep 2020 00:44:49
User entered '03 Sep 2020 20:44'	System	04 Sep 2020 00:44:49

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 4'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

[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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:29', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '32d9dad9-89ba-45b1-98dc-94be292b1075'	System	04 Sep 2020 23:05:56
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 23:05:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:32', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '32d9dad9-89ba-45b1-98dc-94be292b1075'	System	04 Sep 2020 23:05:56
User entered 'No (N)'	System	04 Sep 2020 23:05:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:37', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '32d9dad9-89ba-45b1-98dc-94be292b1075'	System	04 Sep 2020 23:05:56
User entered 'No (N)'	System	04 Sep 2020 23:05:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:42', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '32d9dad9-89ba-45b1-98dc-94be292b1075'	System	04 Sep 2020 23:05:56
User entered 'None (1)'	System	04 Sep 2020 23:05:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '32d9dad9-89ba-45b1-98dc-94be292b1075'	System	04 Sep 2020 23:05:56
User entered '04 Sep 2020 19:05'	System	04 Sep 2020 23:05:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 5'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:42:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '948309c5-f6ad-4f3a-8a9b-613aa2bc732b'	System	05 Sep 2020 23:43:32
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 23:43:32

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '948309c5-f6ad-4f3a-8a9b-613aa2bc732b'	System	05 Sep 2020 23:43:32
User entered 'No (N)'	System	05 Sep 2020 23:43:32

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:06', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '948309c5-f6ad-4f3a-8a9b-613aa2bc732b'	System	05 Sep 2020 23:43:32
User entered 'No (N)'	System	05 Sep 2020 23:43:32

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '948309c5-f6ad-4f3a-8a9b-613aa2bc732b'	System	05 Sep 2020 23:43:32
User entered 'None (1)'	System	05 Sep 2020 23:43:32

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:27', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '948309c5-f6ad-4f3a-8a9b-613aa2bc732b'	System	05 Sep 2020 23:43:32
User entered '05 Sep 2020 19:43'	System	05 Sep 2020 23:43:32

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 6'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

[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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '97508007-102c-4781-afaf-234ce81fdb12'	System	06 Sep 2020 23:57:04
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '97508007-102c-4781-afaf-234ce81fdb12'	System	06 Sep 2020 23:57:04
User entered 'No (N)'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:34', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '97508007-102c-4781-afaf-234ce81fdb12'	System	06 Sep 2020 23:57:04
User entered 'No (N)'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '97508007-102c-4781-afaf-234ce81fdb12'	System	06 Sep 2020 23:57:04
User entered 'None (1)'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '97508007-102c-4781-afaf-234ce81fdb12'	System	06 Sep 2020 23:57:04
User entered '06 Sep 2020 19:57'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 7'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:37:42', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'cc450744-1ba5-433d-8aff-4ea80f9f1122'	System	07 Sep 2020 23:38:09
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:36:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'cc450744-1ba5-433d-8aff-4ea80f9f1122'	System	07 Sep 2020 23:38:09
User entered 'No (N)'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:36:56', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'cc450744-1ba5-433d-8aff-4ea80f9f1122'	System	07 Sep 2020 23:38:09
User entered 'No (N)'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:37:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'cc450744-1ba5-433d-8aff-4ea80f9f1122'	System	07 Sep 2020 23:38:09
User entered 'None (1)'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'cc450744-1ba5-433d-8aff-4ea80f9f1122'	System	07 Sep 2020 23:38:09
User entered '07 Sep 2020 19:38'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:00', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6'	System	01 Sep 2020 17:31:35
User entered 'None (0)'	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6'	System	01 Sep 2020 17:31:35
User entered 'None (0)'	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:06', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6'	System	01 Sep 2020 17:31:35
User entered 'None (0)'	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:10', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6'	System	01 Sep 2020 17:31:35
User entered 'None (0)'	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6'	System	01 Sep 2020 17:31:35
User entered 'None (0)'	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:17', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6'	System	01 Sep 2020 17:31:35
User entered 'None (0)'	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6'	System	01 Sep 2020 17:31:35
User entered 'No (N)'	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6'	System	01 Sep 2020 17:31:35
User entered '01 Sep 2020 13:31'	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:15'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:45'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:21', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a'	System	01 Sep 2020 23:07:55
User entered 'None (0)'	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a'	System	01 Sep 2020 23:07:55
User entered 'None (0)'	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a'	System	01 Sep 2020 23:07:55
User entered 'None (0)'	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a' User entered 'None (0)'	System	01 Sep 2020 23:07:55
	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:34', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a'	System	01 Sep 2020 23:07:55
User entered 'None (0)'	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:37', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a'	System	01 Sep 2020 23:07:55
User entered 'None (0)'	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:41', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a'	System	01 Sep 2020 23:07:55
User entered 'No (N)'	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a'	System	01 Sep 2020 23:07:55
User entered '01 Sep 2020 19:07'	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 16:40'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 2'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'No interference with activity (1)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:55:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'None (0)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'No interference with activity (1)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'None (0)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:55:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:55:07', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'No interference with activity (1)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:56:19', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'No (N)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:56:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered '02 Sep 2020 19:56'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 3'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:54', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered 'None (0)'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:56', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered 'None (0)'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:00', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered 'No interference with activity (1)'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:04', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered 'No interference with activity (1)'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:07', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered 'None (0)'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:10', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered 'None (0)'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:14', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered 'No (N)'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered '03 Sep 2020 20:45'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 4'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56'	System	04 Sep 2020 23:07:55
User entered 'None (0)'	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:06:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56'	System	04 Sep 2020 23:07:55
User entered 'None (0)'	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:06:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56'	System	04 Sep 2020 23:07:55
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:07:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56'	System	04 Sep 2020 23:07:55
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:06:39', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56'	System	04 Sep 2020 23:07:55
User entered 'None (0)'	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:07:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56'	System	04 Sep 2020 23:07:55
User entered 'None (0)'	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:06:47', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56'	System	04 Sep 2020 23:07:55
User entered 'No (N)'	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:07:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56'	System	04 Sep 2020 23:07:55
User entered '04 Sep 2020 19:07'	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 5'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:32', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae'	System	05 Sep 2020 23:44:04
User entered 'None (0)'	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:35', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae'	System	05 Sep 2020 23:44:04
User entered 'None (0)'	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:40', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae'	System	05 Sep 2020 23:44:04
User entered 'None (0)'	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:44', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae'	System	05 Sep 2020 23:44:04
User entered 'No interference with activity (1)'	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:47', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae'	System	05 Sep 2020 23:44:04
User entered 'None (0)'	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae'	System	05 Sep 2020 23:44:04
User entered 'None (0)'	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae'	System	05 Sep 2020 23:44:04
User entered 'No (N)'	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:44:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae'	System	05 Sep 2020 23:44:04
User entered '05 Sep 2020 19:44'	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 6'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:20', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'No interference with activity (1)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'None (0)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:27', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'None (0)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'No interference with activity (1)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'None (0)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'None (0)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:39', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'No (N)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered '06 Sep 2020 19:57'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 7'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'None (0)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:29', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'None (0)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:35', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'None (0)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:50', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'No interference with activity (1)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:54', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'None (0)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'None (0)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:39:10', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'No (N)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:39:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered '07 Sep 2020 19:39'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Sep 2020 23:57:04
User entered 'Day 8'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 23:38:09
User entered 'Day 9'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Sep 2020 23:57:52
User entered 'Day 8'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 23:39:29
User entered 'Day 9'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Sep 2020 23:57:04
User entered 'Day 8'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 23:38:09
User entered 'Day 9'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:38:09

US3412125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:59:57

US3412125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 20:59:57

US3412125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 20:59:57

US3412125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:59:57

US3412125

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 21:00:05

US3412125

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:00:05

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 64'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:01:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-aebc-4ca8-98c9-ae33d0477f47'	System	07 Oct 2020 22:02:46
User entered 'Yes (Y)'	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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 (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:01:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-aebc-4ca8-98c9-ae33d0477f47'	System	07 Oct 2020 22:02:46
User entered 'No (N)'	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:02:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-aebc-4ca8-98c9-ae33d0477f47'	System	07 Oct 2020 22:02:46
User entered 'No (N)'	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:02:11', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-aebc-4ca8-98c9-ae33d0477f47'	System	07 Oct 2020 22:02:46
User entered 'Yes (Y)'	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:02:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-aebc-4ca8-98c9-ae33d0477f47'	System	07 Oct 2020 22:02:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:02:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-ae33d0477f47'	System	07 Oct 2020 22:02:46
User entered '07 Oct 2020 18:02:36'	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Oct 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 Oct 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Oct 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 Oct 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User closed query 'Not added as AEs - please update and add to AE since lasted beyond Day 7' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:09:32
User closed query 'Subject had hyperglycemia and hyponatremia during hospitalization - please review source and add AEs' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:09:29
Query 'Not added as AEs - please update and add to AE since lasted beyond Day 7' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:30:59
Query 'Subject had hyperglycemia and hyponatremia during hospitalization - please review source and add AEs' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:30:46
User opened query 'Not added as AEs - please update and add to AE since lasted beyond Day 7' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:53:24
User closed query 'Per Dose 1 diary, subject had muscle aches and joint aches Day 3 - Day 8 Please review diary/source and capture as AE since beyond Day 7' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:53:24
User opened query 'Subject had hyperglycemia and hyponatremia during hospitalization - please review source and add AEs' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:52:17
Query 'Per Dose 1 diary, subject had muscle aches and joint aches Day 3 - Day 8 Please review diary/source and capture as AE since beyond Day 7' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 14:44:33
User opened query 'Per Dose 1 diary, subject had muscle aches and joint aches Day 3 - Day 8 Please review diary/source and capture as AE since beyond Day 7' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 13:38:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 14:05:03

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:58:49
User entered 'USA-US061-2020-mRNA-1273-P301000005'	System	10 Sep 2020 16:58:33
User entered 'New'	(b) (4), (b) (6)	10 Sep 2020 16:58:33

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'PV query: Please clarify the event reported as MVA. Please define MVA. ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:08:37
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 13:17:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 13:17:43
Data point term sent to Coder	System	21 Sep 2020 13:17:02
Query 'PV query: Please clarify the event reported as MVA. Please define MVA. ' answered with 'motor vehicle accident ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	21 Sep 2020 13:16:25
Coding entries removed.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 13:16:08
User entered 'Motor Vehicle Accident' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Sep 2020 13:16:08
User opened query 'PV query: Please clarify the event reported as MVA. Please define MVA. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:21:11
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 10:22:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 10:22:34
Data point term sent to Coder	System	09 Sep 2020 14:09:11
User entered 'MVA'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Sep 2020 14:16:05
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 14:16:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Sep 2020 14:09:01
User entered '08 Sep ' (non-conformant).	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios	16 Oct 2020 15:49:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR-RQ: Site's response noted. However, a Motor Vehicle Accident is not expected to have a duration of more than a single date. The injuries from the accident might be ongoing but the event of the motor vehicle accident is just a one time event and not expected to have a duration of more than 1 day. Please review and update as appropriate or provide further clarification.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:15:51
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:46:37
User closed query 'As discussed, motor vehicle accident should have a single stop and start date that is a single event. Please have PI review. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:46:33
Query 'As discussed, motor vehicle accident should have a single stop and start date that is a single event. Please have PI review. ' answered with 'This date has been changed and agreed upon that even though medical records state a separate start and end date that the action of the vehicle accident should have the same start and end date.' (Site from CRA).	Steven Anderson (b) (4)	18 Nov 2020 21:29:51
User entered '08 Sep 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	18 Nov 2020 21:28:55
User opened query 'As discussed, motor vehicle accident should have a single stop and start date that is a single event. Please have PI review. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:37:32
Query 'Please discuss with PI as MVA is a single event and should have same start and stop date' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:10:53
User opened query 'Please discuss with PI as MVA is a single event and should have same start and stop date' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:10:37
User closed query 'Should stop date be 8 Sep 2020 since MVA is a single event?' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:10:37

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per DM CLR-RQ: Site's response noted. However, a Motor Vehicle Accident is not expected to have a duration of more than a single date. The injuries from the accident might be ongoing but the event of the motor vehicle accident is just a one time event and not expected to have a duration of more than 1 day. Please review and update as appropriate or provide further clarification.' answered with 'as per hospital records and SUB-I discretion the AE date will not be changed as it is stated on hospital discharge date started on 08 sep 2020 and date resolved 01 oct 2020' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:55:00
User opened query 'Per DM CLR-RQ: Site's response noted. However, a Motor Vehicle Accident is not expected to have a duration of more than a single date. The injuries from the accident might be ongoing but the event of the motor vehicle accident is just a one time event and not expected to have a duration of more than 1 day. Please review and update as appropriate or provide further clarification.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:07:24
Query 'Should stop date be 8 Sep 2020 since MVA is a single event?' answered with 'as per hospital discharge papers date resolved 01 oct 2020' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:14:51
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 18:35:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User opened query 'Should stop date be 8 Sep 2020 since MVA is a single event?' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:33:35
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Oct 2020 15:49:12
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	16 Oct 2020 15:49:12
User entered '01 Oct 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:49:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).		16 Oct 2020 15:47:46
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:19:50
	System	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 14:17:25
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 14:16:05
User entered '1'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
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)	10 Sep 2020 08:48:31
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 'Will provide further information when available ' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 14:17:14
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Sep 2020 14:09:01
User entered '1'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:04:49
Query 'PV Query: Please provide the hospital discharge date when available.' answered with '01 oct 2020' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:49:25
User entered '01 Oct 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:47:46
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:20:48
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:03:55
Query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' answered with 'yes ICU' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:49:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:47:46
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 06:59:55
User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:20:58
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Will update when hospital records are available ' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 14:13:41
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	09 Sep 2020 14:09:01
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Admitted to ICU? is Yes, however System Number of Days in ICU is missing. Please review and reconcile.' (Site from System).		16 Oct 2020 15:49:46
Query 'Admitted to ICU? is Yes, however Number of System Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).		16 Oct 2020 15:49:46
User entered '10' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:49:46
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	16 Oct 2020 15:47:46
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:37:50
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:05:02
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'tracheostomy, bronchoscopy, endoscopic gastrostomy tube placement, closed right tibia-fibula fracture, con meds updated' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 16:13:52
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios	16 Oct 2020 15:47:46
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:20:38
User entered '1'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:33:56
Query 'Conmeds related to this AE are recorded. Please update as appropriate' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:33:49
User opened query 'Conmeds related to this AE are recorded. Please update as appropriate' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:33:04
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:37:50
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	16 Oct 2020 15:47:46
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:33:55
Query 'Concomitant procedures related to this AE are recorded. Please update as appropriate' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:33:50
User opened query 'Concomitant procedures related to this AE are recorded. Please update as appropriate' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:33:17
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:44
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:37:50
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	16 Oct 2020 15:47:46
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

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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)	22 Oct 2020 18:33:49
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:05:08
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:50:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:47:46
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:20:07
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

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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)	22 Oct 2020 18:33:49
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 14:09:01

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[Narrative](#)

Audit	User	Time (GMT)
User entered '71 YOF HISTORY OF OPEN SUBTOTAL COLECTOMY WITH END ILEOSTOMY S/P REVERSAL WITH LOWER MIDLINE INCISIONAL HERNIA S/P LAPAROSCOPIC REPAIR WITH MESH WHO PRESENTS S/P MVC ON SEP 8,2020 WITH MULTIPLE INJURIES INCLUDING SUBARACHNOID HEMORRHAGE, BLUNT CEREBROVASCULAR INJURY WITH SUBSEQUENT STROKE AND SEIZURE, GRADE IV LIVER LACERATION, AND RIGHT TIBIAL AND FIBULAR FRACTURES. GIVEN HER ANTICIPATED PROLONGED NEED FOR VENTILATORY SUPPORT AND ENTERAL NUTRITION A TRACHEOSTOMY AND PEG WERE PERFORMED. OF NOTE, THE PATIENT ALSO HAS AN EXTENSIVE ABDOMINAL SURGICAL HISTORY INCLUDING SUBTOTAL COLECTOMY WITH ILEORECTAL ANASTOMOSIS AND SUBSEQUENT VENTRAL HERNIA REPAIR WITH PERMANENT MESH.'	Steven Anderson (b) (4)	24 Nov 2020 19:45:59
reason for change: Data Entry Error		
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:37:29
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:43:38
User closed query 'please update narrative' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:55:46

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'these records will be sent tomorrow. per monitor all queries must be closed.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 20:56:50
Query 'please update narrative' answered with 'narrative has been updated' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 20:56:10
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 20:55:43
User entered '71 yoF history of open subtotal colectomy with end ileostomy s/p reversal with lower midline incisional hernia s/p laparoscopic repair with mesh who presents s/p MVC on sep 8,2020 with multiple injuries including subarachnoid hemorrhage, blunt cerebrovascular injury with subsequent stroke and seizure, grade v liver laceration, and right tibial and fibular fractures. Given her anticipated prolonged need for ventilatory support and enteral nutrition a tracheostomy and PEG were performed. Of note, the patient also has an extensive abdominal surgical history including subtotal colectomy with ileorectal anastomosis and subsequent ventral hernia repair with permanent mesh.' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:55:43
User opened query 'please update narrative' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:14:48
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 16:30:37
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:54:17

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'The hospital discharge paperwork did not include any laboratory results' (Site from Safety).	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:37:16
User closed query 'PV Query: It was reported the subject was in grave condition. Please consider reporting the subject's injuries as additional SAEs. It is the subject's injuries that led to life-threatening, grave condition, not MVA.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:05:24
User closed query 'PV Query: Please clarify if subject was driver for motor vehicle accident. If so, did a medical condition precipitate a driver error?' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:04:57
Query 'PV Query: It was reported the subject was in grave condition. Please consider reporting the subject's injuries as additional SAEs. It is the subject's injuries that led to life-threatening, grave condition, not MVA.' answered with 'updated' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 16:14:30
Query 'PV Query: Please clarify if subject was driver for motor vehicle accident. If so, did a medical condition precipitate a driver error?' answered with 'subject did not have a medical that caused this motor vehicle accident' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:56:26
User opened query 'PV Query: It was reported the subject was in grave condition. Please consider reporting the subject's injuries as additional SAEs. It is the subject's injuries that led to life-threatening, grave condition, not MVA.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 17:07:42
User opened query 'PV Query: Please clarify if subject was driver for motor vehicle accident. If so, did a medical condition precipitate a driver error?' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:21:34
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:20:25
User entered 'Subjects spouse called stating that subject was in a MVA on 08sep2020 and in grave condition. Will request medical records.'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 15:47:46
User entered '0'	System	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:35:11
User entered 'USA-US061-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	20 Oct 2020 12:35:06

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Craniocerebral injury, LLT: Traumatic brain injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:41:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:41:31
Data point term sent to Coder	System	19 Oct 2020 20:40:29
User entered 'Traumatic brain injury'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '23 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:39:38
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Oct 2020 20:40:31
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	19 Oct 2020 20:40:31
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Oct 2020 20:39:38
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:39:38
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Oct 2020 20:40:31
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Oct 2020 20:39:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		19 Oct 2020 20:40:31
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		19 Oct 2020 20:40:31
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:40:31
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	19 Oct 2020 20:39:38
User entered '0'	Mylene Asmar-Rios	19 Oct 2020 20:39:38
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	19 Oct 2020 20:40:31
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	19 Oct 2020 20:40:31
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	19 Oct 2020 20:39:38
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:15:35
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:24:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:24:20
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:39:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:08:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:53:04
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'this has been updated to indicate con meds were taken for it' (Site from DM).	Steven Anderson (b) (4)	10 Nov 2020 21:24:02
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 21:19:47
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:17:21
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:13:27
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:56:50
User closed query 'per source amantadine HCL given for traumatic brain injury - please confirm and update action taken on thsi CRF' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:56:47
Query 'per source amantadine HCL given for traumatic brain injury - please confirm and update action taken on thsi CRF' answered with 'this has been updated to indicate con meds were taken for it' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 21:24:06
User entered '1' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 21:19:47
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 15:17:23
User opened query 'per source amantadine HCL given for traumatic brain injury - please confirm and update action taken on thsi CRF' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:30:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:41:40
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:40:31
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'function of subject confusion, weakness' reason for change: Data Entry Error	Mylene Asmar-Rios	21 Oct 2020 16:30:40
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	19 Oct 2020 20:41:40
User entered empty.	System	19 Oct 2020 20:40:31
	Mylene Asmar-Rios	19 Oct 2020 20:39:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:41:58
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Oct 2020 20:41:40
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Oct 2020 20:41:40
User entered 'Subject was in Moto Vehicle Accident' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:41:40
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Oct 2020 20:39:38
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:35:58
User entered 'USA-US061-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	20 Oct 2020 12:35:53

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Embolic stroke, LLT: Embolic stroke - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 23:28:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 23:28:25
Data point term sent to Coder	System	19 Oct 2020 20:44:33
User entered 'Multiple left hemisphere Embolic Infarct'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios	19 Oct 2020 20:43:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:45:40
Query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' answered with 'Site is closing all queries like this. This reflects back on us stating we have open queries and we get told to do them consistently. site will update information if these SAE's close' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:26:01
User opened query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:13:45
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:43:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:33:10
User entered empty.	System	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV query: Please confirm admission date as MULTIPLE LEFT HEMISPHERE EMBOLIC INFARCT has an admission of 03 Sep 2020.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:45:49
	(b) (4), (b) (6)	11 Nov 2020 04:53:31
User closed query 'hospital admission on 8 Sep 2020 per source - please confirm and correct' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 04:53:29
Query 'hospital admission on 8 Sep 2020 per source - please confirm and correct' answered with 'date has been updated. all admission date for all SAE's should be 08-sep-2020' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 21:27:41
Query 'PV query: Please confirm admission date as MULTIPLE LEFT HEMISPHERE EMBOLIC INFARCT has an admission of 03 Sep 2020.' answered with 'date has been updated. all admission date for all SAE's should be 08-sep-2020' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:27:38
User entered '08 Sep 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 21:27:18
User opened query 'hospital admission on 8 Sep 2020 per source - please confirm and correct' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:54:06
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 15:19:05
User opened query 'PV query: Please confirm admission date as MULTIPLE LEFT HEMISPHERE EMBOLIC INFARCT has an admission of 03 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:14:37
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '03 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Oct 2020 20:43:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:25:10
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mylene Asmar-Rios	22 Oct 2020 21:25:10
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:43:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:10:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:53:46
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 22:07:01
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	10 Nov 2020 22:07:01
Query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' answered with 'Per medical records no treatments or procedures were specifically given for this SAE. Subject had multiple conditions that could have resulted in this/ had similar treatments.' (Site from DM).	(b) (4)	
	Steven Anderson (b) (4)	10 Nov 2020 21:36:19
User opened query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:14:28
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:53:52
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 22:07:01
User entered '1' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 22:07:01
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:33:25
User closed query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:45:58
Query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained.' answered with 'Site will not leave this query open. site is being pointed out for leaving these open and being told to address by monitors. site will address once more information has been updated.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:37:09
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:14:04
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Subject was in Motor Vehicle Accident'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:37:03
User entered 'USA-US061-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	20 Oct 2020 12:36:59

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery thrombosis, LLT: Intraluminal coronary thrombosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:10:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:10:52
User closed query 'PV Query: The current event contains two event terms. Please separate the verbatim term into two SAEs to represent the two events of 'Carotid artery dissection' and 'Carotid artery thrombus'. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:46:51
Query 'PV Query: The current event contains two event terms. Please separate the verbatim term into two SAEs to represent the two events of 'Carotid artery dissection' and 'Carotid artery thrombus'. ' answered with 'Per medical records this was one diagnosis. Medication was also given to treat both. site will not update to two separate SAE's' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 21:50:34
User opened query 'PV Query: The current event contains two event terms. Please separate the verbatim term into two SAEs to represent the two events of 'Carotid artery dissection' and 'Carotid artery thrombus'. ' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 15:24:01
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Data point term sent to Coder	System	21 Oct 2020 15:15:19
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of LEFT INTERCAROTID ARTERY DISSECTION and one of INTRALUMINAL CORONARY THROMBUS' (Site from System).	System	21 Oct 2020 15:15:10
Query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of LEFT INTERCAROTID ARTERY DISSECTION and one of INTRALUMINAL CORONARY THROMBUS' answered with 'its one diagnosis no further breakup needed' (Site from System).	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:15:10

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of LEFT INTERCAROTID ARTERY DISSECTION and one of INTRALUMINAL CORONARY THROMBUS' (Site from System).	Coder Import (b) (4)	21 Oct 2020 14:37:29
Data point term sent to Coder	System	20 Oct 2020 14:44:43
User closed query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' (Site from System).	System	20 Oct 2020 14:44:21
Query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' answered with 'updated. ' (Site from System).	Jacob sekinger (b) (4)	20 Oct 2020 14:44:21
User entered 'LEFT INTERCAROTID ARTERY dissection with intraluminal thrombus' reason for change: Data Entry Error	Jacob sekinger (b) (4)	20 Oct 2020 14:44:10
User opened query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' (Site from System).	Coder Import (b) (4)	20 Oct 2020 08:59:27
Data point term sent to Coder	System	19 Oct 2020 20:50:42
User entered 'Left intercarotid artery'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:49:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:47:04
Query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained. ' answered with 'Site will nto leave this open due to monitors requesting all queries be closed. Site will address once SAE closes' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:44:11
User opened query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:15:21
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:49:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:34:40
User entered empty.	System	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Oct 2020 20:50:09
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Oct 2020 20:49:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
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).		19 Oct 2020 20:51:00
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		19 Oct 2020 20:51:00
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		19 Oct 2020 20:50:09
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		19 Oct 2020 20:50:09
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	19 Oct 2020 20:50:09
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:50:09
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	19 Oct 2020 20:49:49
User entered '0'	Mylene Asmar-Rios	19 Oct 2020 20:49:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:51:00
User entered empty.	(b) (4)	
	Mylene Asmar-Rios	19 Oct 2020 20:49:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	19 Oct 2020 20:50:09
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	19 Oct 2020 20:50:09
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	19 Oct 2020 20:49:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:54:19
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:25:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:25:58
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:49:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 11:59:19
	(b) (4), (b) (6)	11 Nov 2020 04:54:29
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'this has been updated due to con med being used for this SAE' (Site from DM). DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 21:44:54
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 21:44:30
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' canceled (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:12:39
	(b) (4), (b) (6)	28 Oct 2020 15:11:42
User opened query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:10:45
	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:54:31
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 21:44:30
User entered '1' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 21:44:30
DataPoint Verified.	Steven Anderson (b) (4)	10 Nov 2020 21:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios	19 Oct 2020 20:49:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:34:54
User closed query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:47:11
Query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained.' answered with 'Site will not leave query open. these events may not resolve by end of trial and monitors are requesting all queries closed for SAE. please advise this with internal team before putting another query.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:46:07
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:15:37
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:37:51
User entered 'USA-US061-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	20 Oct 2020 12:37:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Cervical vertebral fracture, LLT: Cervical vertebral fracture C7 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:51:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:51:31
Data point term sent to Coder	System	19 Oct 2020 20:53:44
User entered 'CERVICAL 7 FRACTURE'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 20:53:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 20:53:01
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:53:01
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 20:52:51
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios	19 Oct 2020 20:52:51
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:47:37
Query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' answered with 'Site will not leave query open. these events may not resolve by end of trial and monitors are requesting all queries closed for SAE. please advise this with internal team before putting another query.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:51:05
User opened query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:12:10
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:31:48
User entered empty.	System	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Oct 2020 20:52:51
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:54:49
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:26:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:26:47
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:52:51
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:54:56
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 22:08:44
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	10 Nov 2020 22:08:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios	19 Oct 2020 20:52:51
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 11:59:47
	(b) (4), (b) (6)	11 Nov 2020 04:54:55
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'this has been updated due to no con procedure being performed. there was no noted procedures or anything in medical records.' (Site from DM). DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 22:08:50
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 22:08:44
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:08:32
	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:31:17
User closed query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:47:52
Query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained' answered with 'Site will not leave query open. these events may not resolve by end of trial and monitors are requesting all queries closed for SAE. please advise this with internal team before putting another query.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:51:15
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:12:27
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:38:51
User entered 'USA-US061-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	20 Oct 2020 12:38:43

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Rib fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:11:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:11:33
Data point term sent to Coder	System	19 Oct 2020 20:56:51
User entered 'NONDISPLACED RIB FRACTURES RIGHT 1-2'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:56:28
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:02:02
Query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' answered with 'Site will not leave these open anymore due to site being told to close all queries. if these are to be left open there has to be an internal communication between you and monitors.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:09:55
User opened query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:13:21
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:56:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:12:16
User closed query 'grade 2 per source? Please review and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:12:14
Query 'grade 2 per source? Please review and update as appropriate' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:16:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:16:24
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 18:43:04
User opened query 'grade 2 per source? Please review and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:42:55
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 12:14:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		21 Oct 2020 15:14:06
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'no SAE' (Site from System).	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:13:48
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	21 Oct 2020 15:07:41
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	21 Oct 2020 15:07:41
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
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).		21 Oct 2020 15:14:06
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		21 Oct 2020 15:14:06
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios	21 Oct 2020 15:14:06
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).	(b) (4) System	21 Oct 2020 15:07:41
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:27:27
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mylene Asmar-Rios	22 Oct 2020 21:27:27
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:56:28
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:55:25
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 22:15:08
User entered '1' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 22:15:08
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 11:58:22
	(b) (4), (b) (6)	11 Nov 2020 04:55:27
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'site is not noting any procedures performed for this ae. sit ehas changed data' (Site from DM). DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 22:15:56
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 22:15:08
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:15:07
	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:02:06
Query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained' answered with 'Site will not leave these open anymore due to site being told to close all queries. if these are to be left open there has to be an internal communication between you and monitors.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:10:03
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 15:07:41
User entered '1'	System	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:40:03
User entered 'USA-US061-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	20 Oct 2020 12:39:56

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Staphylococcal infections, PT: Pneumonia staphylococcal, LLT: Pneumonia MRSA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:39:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:39:29
Data point term sent to Coder	System	19 Oct 2020 20:58:54
User entered 'MRSA PNEUMONIA'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios	19 Oct 2020 20:58:10
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '29 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:58:10
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:55:40
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:28:12
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:28:12
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[AEID](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please update the event term to the final diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:38:34
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:40:41
User entered 'USA-US061-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	20 Oct 2020 12:40:37

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non STEMI - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:44:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:44:01
Data point term sent to Coder	System	24 Nov 2020 18:51:12
Query 'For coding purposes, this entry references two events that while related, must be reported separately as the combined events are not referenced together in the standard dictionary, please provide a single diagnosis or split and report separately to capture coding for all the terms.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:51:01
User opened query 'For coding purposes, this entry references two events that while related, must be reported separately as the combined events are not referenced together in the standard dictionary, please provide a single diagnosis or split and report separately to capture coding for all the terms.' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:51:51
User closed query 'PV query: Please update the term "NSTEMI vs cardiac contusion ". Did the subject experience NSTEMI or cardiac contusion or both? If so, please report as applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	11 Nov 2020 19:05:25
Query 'PV query: Please update the term "NSTEMI vs cardiac contusion ". Did the subject experience NSTEMI or cardiac contusion or both? If so, please report as applicable.' answered with 'unable to decipher due to medical records.' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 22:34:05
User opened query 'PV query: Please update the term "NSTEMI vs cardiac contusion ". Did the subject experience NSTEMI or cardiac contusion or both? If so, please report as applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	23 Oct 2020 12:07:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	22 Oct 2020 18:33:49
Data point term sent to Coder	System	22 Oct 2020 14:12:58
User closed query 'DM-Coding: Please provide a single confirmed diagnosis (please update to Non STEMI if it was) or record the suspected diagnoses/symptoms separately. ' (Site from System).	System	22 Oct 2020 14:12:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
Query 'DM-Coding: Please provide a single confirmed diagnosis (please update to Non STEMI if it was) or record the suspected diagnoses/symptoms separately. ' answered with 'AS PER HOSPITAL RECORDS NON STEMI VS CARDIAC CONTUSION WAS THE DIAGNOSES GIVEN THEREFORE IT CAN NOT BE BROKEN APART' (Site from System).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:12:05
Data point term sent to Coder	System	22 Oct 2020 14:11:56
User entered 'NON STEMI VS CARDIAC CONTUSION' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:11:21
User opened query 'DM-Coding: Please provide a single confirmed diagnosis (please update to Non STEMI if it was) or record the suspected diagnoses/symptoms separately. ' (Site from System).	Coder Import (b) (4) (b) (4)	22 Oct 2020 08:36:24
Data point term sent to Coder	System	21 Oct 2020 15:16:20
User closed query 'DM-Coding: Please provide a single confirmed diagnosis or record the suspected diagnoses/symptoms separately. ' (Site from System).	System	21 Oct 2020 15:16:19
Query 'DM-Coding: Please provide a single confirmed diagnosis or record the suspected diagnoses/symptoms separately. ' answered with 'its one diagnosis ' (Site from System).	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:16:19
User opened query 'DM-Coding: Please provide a single confirmed diagnosis or record the suspected diagnoses/symptoms separately. ' (Site from System).	Coder Import (b) (4) (b) (4)	20 Oct 2020 09:04:28
Data point term sent to Coder	System	19 Oct 2020 21:00:58
User entered 'NSTEMI VS CARDIAC CONTUSION'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Oct 2020 16:45:11
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:45:11
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Oct 2020 16:44:52
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	21 Oct 2020 16:44:52
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	21 Oct 2020 16:44:52
User entered '01 Oct 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:44:52
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	21 Oct 2020 16:32:52
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 21:00:38
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:12:55
User closed query 'Admission 8 Sep 2020 per source? Please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:12:52
Query 'Admission 8 Sep 2020 per source? Please review and update accordingly' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:19:09
User entered '08 Sep 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:18:41
User opened query 'Admission 8 Sep 2020 per source? Please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 18:44:28
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:56:00
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:19:52
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:19:52
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 21:00:38
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:17:18
Query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' answered with 'per medical record cardiologist said she is not a candidate for treatment due to multiple serious injuries.' (Site from DM).	Steven Anderson (b) (4)	10 Nov 2020 22:36:48
User opened query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:16:09
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:32:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:41:19
User entered 'USA-US061-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	20 Oct 2020 12:41:13

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if liver laceration was grade IV (per event term) or grade V per event narrative' answered with 'This was updated to Grade IV' (Site from Safety).	Steven Anderson (b) (4)	24 Nov 2020 19:46:39
User opened query 'PV Query: Please confirm if liver laceration was grade IV (per event term) or grade V per event narrative' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:39:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Traumatic liver injury, LLT: Liver laceration - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 21:59:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 21:59:33
Data point term sent to Coder	System	19 Oct 2020 21:03:04
User entered 'GRADE IV LIVER LACERATION'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios	19 Oct 2020 21:02:23
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 21:02:23
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:06:09
Query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained. ' answered with 'Site will not leave these open any longer. please see other queries on why' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:44:06
User opened query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:16:45
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 21:02:23
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:35:46
User entered empty.	System	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:56:13
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:29:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:29:09
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 21:02:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:14:43
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'blood transfusion was the medical treatment for the liver laceration' (Site from DM).	Steven Anderson (b) (4)	10 Nov 2020 22:53:04
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:09:14
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:35:59
User closed query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:06:24
Query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained.' answered with 'Site will no longer leave these queries open. please see other queries on why.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:44:29
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:16:27
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:42:53
User entered 'USA-US061-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	20 Oct 2020 12:42:49

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Blood loss anaemia, LLT: Acute post hemorrhagic anemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:08:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:08:28
Data point term sent to Coder	System	19 Oct 2020 21:07:09
User entered 'ACUTE POST HEMORRHAGIC ANEMIA'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 21:07:04
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:07:09
Query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' answered with 'Site will not leave this open please refer to other queries on why' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:53:37
User opened query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:11:28
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained. ' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:29:46
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:29:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:30:02
User entered empty.	System	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Oct 2020 21:07:04
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:13:26
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:29:54
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:29:54
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 21:07:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:30:25
User closed query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:07:17
Query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained' answered with 'site will not leave these open anymore please see other queries on why' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:53:54
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:11:15
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'SUBJECT WAS INVOLVED IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Lower limb fracture, LLT: Lower limb fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 09:21:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 09:21:31
Data point term sent to Coder	System	21 Oct 2020 16:49:07
User entered 'Right Tib/ Fib Fracture'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:09:09
User closed query 'Please clarify - this was injury from MVA not after so start date should be 8 Sep 2020? Repair was 13 Sep 2020' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:09:06
Query 'Please clarify - this was injury from MVA not after so start date should be 8 Sep 2020? Repair was 13 Sep 2020' answered with 'As per hospital discharge papers this was actually found incidentally and might be age related ' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:21:27
User opened query 'Please clarify - this was injury from MVA not after so start date should be 8 Sep 2020? Repair was 13 Sep 2020' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:50:22
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 18:47:14
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	21 Oct 2020 16:48:10
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	21 Oct 2020 16:48:10
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	21 Oct 2020 16:48:10
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:13:42
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:22:38
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:22:38
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	21 Oct 2020 16:48:10
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:52:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:52:19
Data point term sent to Coder	System	22 Oct 2020 21:34:06
User entered 'HRYPEGLYCEMUA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[None](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:41:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:41:26
Data point term sent to Coder	System	22 Oct 2020 21:40:24
User entered 'HYPONATREMIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[None](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 26 Nov 2020 09:25:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 21:40:13

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:25:25

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Diary Dose 2, Log Line #5 e-diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:13:44
Query 'Per CDM: Diary Dose 2, Log Line #5 e-diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' answered with 'metamucil was taken for this and has been recorded in concomitant medications' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 14:53:42
User opened query 'Per CDM: Diary Dose 2, Log Line #5 e-diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 10:03:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:41:46
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 13:03:37

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:44:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:44:19
Data point term sent to Coder	System	21 Aug 2020 15:42:57
User entered 'AMLODIPINE'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPERTENSION'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '5'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:44:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:44:18
Data point term sent to Coder	System	21 Aug 2020 15:43:00
User entered 'ATENOLOL'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPERTENSION'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:15:32
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'per patient records, this is the correct dosage. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	26 Oct 2020 18:28:33
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:23:05
User entered '35'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 15:42:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 15:42:22
Data point term sent to Coder	System	21 Aug 2020 15:44:03
User entered 'CYCLOBENZAPRINE'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'CHRONIC LOW BACK PAIN'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '5'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'as needed (PRN)'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:03:28
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'MH has been updated' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:56:37
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:24:18
User entered 'UN UNK 2009'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE HYDROCHLORIDE, PRODUCTSYNONYM: DICYCLOMINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:45:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:45:18
Data point term sent to Coder	System	21 Aug 2020 15:45:07
User entered 'DICYCLOMINE HYDROCHLORIDE'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'IRRITABLE BOWEL SYNDROME-D'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '20'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'as needed (PRN)'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2000'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:45:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:45:46
Data point term sent to Coder	System	21 Aug 2020 15:45:08
User entered 'LEVOTHYROXINE'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPOTHYROID'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '75'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'ug (ug)'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:47:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:47:18
Data point term sent to Coder	System	21 Aug 2020 15:46:08
User entered 'LOSARTAN'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPERTENSION'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '100'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:47:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:47:18
Data point term sent to Coder	System	21 Aug 2020 15:46:09
User entered 'MELOXICAM'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'OSTEOARTHRITIS'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '15'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:34:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:34:51
Data point term sent to Coder	System	21 Aug 2020 15:47:15
User entered 'PSEUOBEPHEDRINE'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'SEROUS OTITIS MEDIA'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '120'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2000'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:49:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:49:22
Data point term sent to Coder	System	21 Aug 2020 15:48:23
User entered 'VITAMIN D'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'GENERAL HEALTH'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:14:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'THIS IS AN OTC MEDICATION AND PATIENT DOES NOT KNOW DOSAGE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	10 Nov 2020 20:31:26
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:25:19
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '5 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:49:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:49:22
Data point term sent to Coder	System	21 Aug 2020 15:48:23
User entered 'CALCIUM'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'GENERAL HEALTH'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:16:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'THIS IS AN OTC MEDICATION AND PATIENT DOES NOT KNOW DOSAGE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	10 Nov 2020 20:31:36
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:23:47
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '5 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:05:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:05:35
Data point term sent to Coder	System	22 Sep 2020 13:04:22
User entered 'Tylenol' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:31
Data point term sent to Coder	System	22 Sep 2020 13:03:20
User entered 'Ty;emp;'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'OA'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '500'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'as needed (PRN)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'un UNK 2019'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: PLANTAGO OVATA, PRODUCTSYNONYM: METAMUCIL [PLANTAGO OVATA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:22:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:22:47
Data point term sent to Coder	System	22 Sep 2020 13:36:12
User entered 'Metamucial'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'IBS'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '1'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if the number of PACKETS/SACHET would be a more appropriate dose and unit instead of the number of glass. Update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 12:17:42
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
Query 'Per DM CLR: Please review if the number of PACKETS/SACHET would be a more appropriate dose and unit instead of the number of glass. Update as appropriate. Otherwise, provide clarification.' answered with 'UPDATED TO ADD SACHET' (Site from DM).	Melissa Fuson (b) (4)	10 Nov 2020 20:34:01
	(b) (4)	
User entered 'EIGHT OUNCE GLASS WITH SACHET' reason for change: Data Entry Error	Melissa Fuson (b) (4)	10 Nov 2020 20:33:46
	(b) (4)	
User opened query 'Per DM CLR: Please review if the number of PACKETS/SACHET would be a more appropriate dose and unit instead of the number of glass. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:24:43
User entered 'Eight ounce glass'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '1'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: ADAMANTANE DERIVATIVES, PRODUCT: AMANTADINE HYDROCHLORIDE, PRODUCTSYNONYM: AMANTADINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:30:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:30:24
Data point term sent to Coder	System	22 Oct 2020 14:16:02
User entered 'AMANTADINE HCL'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'TRAUMATIC BRAIN INJURY'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '50/5'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'PER GASTRIC TUBE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 14:55:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 14:55:37
Data point term sent to Coder	System	22 Oct 2020 14:18:04
User entered 'APIRABAN'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'LEFT INTERCAROTID ARTERY DISSECTION WITH NTRALUMINAL THROMBUS'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '5'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'twice daily (BID)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: CARVEDIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 14:27:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 14:27:01
Data point term sent to Coder	System	22 Oct 2020 14:19:11
User entered 'CARVEDIOL'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPERTENSION'	Myelene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '3.125'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'twice daily (BID)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:21:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:21:37
Data point term sent to Coder	System	22 Oct 2020 14:20:15
User entered 'ESOMEPRAZOLE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'GERD'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '40'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'PER GASTRIC TUBE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 14:27:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 14:27:08
Data point term sent to Coder	System	22 Oct 2020 14:21:15
User entered 'FERROUS SULFATE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'ANEMIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '325'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:27:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:27:30
Data point term sent to Coder	System	22 Oct 2020 14:22:17
User entered 'INSULIN GLARGINE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPERGLYCEMIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '20'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'IU (IU)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:37:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:37:34
Data point term sent to Coder	System	22 Oct 2020 14:24:25
User entered 'INSULIN REGULAR'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPERGLYCEMIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0-12'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'IU (IU)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'three times daily (TID)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:27:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:27:42
Data point term sent to Coder	System	22 Oct 2020 14:25:26
User entered 'SODIUM CHLORIDE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPONATREMIA'	Myelene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '2'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'g (g)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'three times daily (TID)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'PER NASOGASTRIC TUBE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:34:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:34:31
Data point term sent to Coder	System	22 Oct 2020 14:26:27
User entered 'PANTAPROZOLE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'GERD'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '40'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2009'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:24:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:24:42
Data point term sent to Coder	System	22 Oct 2020 14:45:12
User entered 'VANCOMYCIN'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'MRSA PNEUMONIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNK'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNKNOWN'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNKNOWN'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '29 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:03:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:03:36
Data point term sent to Coder	System	22 Oct 2020 14:46:14
User entered 'CEFEPIME'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'MRSA PNEUMONIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNK'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNKOWN'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNKOWN'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '29 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:25:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:32:00
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 13:03:42

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:25:25

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered '18 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:35:40

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:25:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'TRACHESTOMY'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:35:40

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'Adverse Event (AE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:35:40

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:25:25

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:35:40

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:25:25

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered '18 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:15

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:25:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'BRONCHOSCOPY'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:15

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'Adverse Event (AE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:15

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:25:25

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:15

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:25:25

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered '18 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:54

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:25:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBE PLACEMENT'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:54

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'Adverse Event (AE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:54

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:25:25

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:54

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:25:25

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:37:17

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:25:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'CLOSED RIGHT TIBIA-FIBULA FRACTURE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:37:17

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'Adverse Event (AE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:37:17

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:25:25

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:37:17

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:25:25

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered '23 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:42:06

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:25:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'BLOOD TRANSFUSION'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:42:06

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:25:25

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'Adverse Event (AE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:42:06

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:25:25

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:42:06

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:11
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:11
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
User entered '10/Sep/2020 12:59'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
User entered '1'	(b) (4), (b) (6)	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:11
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
User entered '22/Sep/2020 09:09'	System	22 Sep 2020 13:09:01

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 14:06:06
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 13:09:01

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:11
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:25:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
User entered '19/Oct/2020 14:07'	System	19 Oct 2020 14:07:01

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:25:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 14:08:03
User entered '1'	(b) (4), (b) (6)	19 Oct 2020 14:07:01

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:11
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:25:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
User entered '20/Oct/2020 12:43'	System	20 Oct 2020 12:43:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:25:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:54:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 12:43:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:11
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:25:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:54:29
User entered '21/Oct/2020 13:55'	System	21 Oct 2020 13:55:15

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:25:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:54:29
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:07:22
User entered '1'	(b) (4), (b) (6)	21 Oct 2020 13:55:15

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:11
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:25:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:54:29
User entered '22/Oct/2020 13:07'	System	22 Oct 2020 13:07:45

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:25:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:54:29
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:05:40
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 13:07:45

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:11
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:25:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:54:29
User entered '23/Oct/2020 16:05'	System	23 Oct 2020 16:06:04

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:25:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:50:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:54:29
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 16:06:04

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:11
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:25:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:44
User entered '11/Nov/2020 17:50'	System	11 Nov 2020 17:50:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:25:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:44
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:56:25
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 17:50:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:11
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:25:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:44
User entered '19/Nov/2020 13:56'	System	19 Nov 2020 18:56:47

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:25:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:44
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 18:56:47