

US3412013 (Prod: New Horizons Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:23:50

All time stamps listed in this document are displayed in GMT

US3412013

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:50

[Participant ID](#)

US3412013

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

US3412013

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
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

US3412013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:50

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	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

US3412013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:23:50

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3412013

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:50

Were any significant conditions reported?

Yes ☒

No ☐

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:50

Condition	HYPERLIPIDEMIA
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)	

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:50

Condition	HYPERTENSION
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)	

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:50

Condition	GERD
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)	_____

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:50

Condition	CHRONIC LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:50

Condition	DIABETES TYPE II
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)	

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:50

Condition	ANXIETY
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)	_____

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:50

Condition	VERTIGO
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:50

Condition	FEVER BLISTERS
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
Stop Month and Year (derived)	
Stop Year (derived)	

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:50

Condition	DYSAUTONOMIA
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:50

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	29 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	12:05 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 12:05
Height (<i>xxx.x</i>)	167.5 cm
Weight (<i>xxx.x</i>)	87.6 kg
BMI (<i>xxx.x</i>)	31.22299 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)	

US3412013

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 2020

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

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:50

Date of assessment (<i>dd MMM yyyy</i>)	29 JUL 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 2008
Date of last menstruation unknown	False

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	SOCIALIZES, SHARED APARTMENT ENTRANCE, AND LIVES IN HIGH RISK COUNTY

US3412013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:50

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

What was the participant's randomization number? 142255

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 ☒

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:50

Height	ND - Not Done
Weight	ND - Not Done

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

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)	29 JUL 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 12:05
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

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)	29 JUL 2020
Time of assessment (00:00-23:59)	13:35 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 13:35
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

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.

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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) 29 JUL 2020

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

Treatment Date and Time (derived) 29 JUL 2020 13:00

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

US3412013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

29 JUL 2020

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

12:25 (24 HR)

Collection date and time (derived)

29 JUL 2020 12:25

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:50

Collection date (<i>dd MMM yyyy</i>)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:37	29 JUL 2020 12:37
Nasopharyngeal Swab 2	No		

US3412013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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

97.3 °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

29 JUL 2020 13:39

PC Open Date & Time

29 JUL 2020 13:20

PC Close Date & Time

29 JUL 2020 15:50

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	29 JUL 2020 20:05
PC Open Date & Time	29 JUL 2020 16:45
PC Close Date & Time	30 JUL 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 12:37

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

31 JUL 2020 12:55

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 18:24

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

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

97.6 °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

02 AUG 2020 13:03

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

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

97.8 °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 AUG 2020 12:38

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 AUG 2020 11:30

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 13:42

PC Open Date & Time

29 JUL 2020 13:20

PC Close Date & Time

29 JUL 2020 15:50

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 20:03

PC Open Date & Time

29 JUL 2020 16:45

PC Close Date & Time

30 JUL 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 12:38

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 12:56

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 18:25

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 13:03

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 14:45

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

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

05 AUG 2020 11:30

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 13:43
PC Open Date & Time	29 JUL 2020 13:20
PC Close Date & Time	29 JUL 2020 15:50

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 20:03
PC Open Date & Time	29 JUL 2020 16:45
PC Close Date & Time	30 JUL 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	30 JUL 2020 12:38
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	31 JUL 2020 12:57
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	01 AUG 2020 18:25
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	02 AUG 2020 13:04
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	03 AUG 2020 14:45
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	05 AUG 2020 11:30
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3412013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

US3412013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

US3412013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	11:06 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:06
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:35
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3412013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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)	26 AUG 2020
What was the treatment time? (00:00-23:59)	12:05 (24 HR)
Treatment Date and Time (derived)	26 AUG 2020 12:05
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

US3412013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	26 AUG 2020
Collection time (<i>00:00-23:59</i>)	11:40 (24 HR)
Collection date and time (derived)	26 AUG 2020 11:40

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:50

Collection date (<i>dd MMM yyyy</i>)			26 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	11:49	26 AUG 2020 11:49
Nasopharyngeal Swab 2	No		

US3412013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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

97.8 °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

26 AUG 2020 12:37

PC Open Date & Time

26 AUG 2020 12:25

PC Close Date & Time

26 AUG 2020 14:55

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	26 AUG 2020 18:59
PC Open Date & Time	26 AUG 2020 15:50
PC Close Date & Time	27 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

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	100.2 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	27 AUG 2020 14:13
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

28 AUG 2020 18:03

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 18:04

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

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

97.6 °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

30 AUG 2020 19:41

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 15:27

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 17:16

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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

26 AUG 2020 12:37

PC Open Date & Time

26 AUG 2020 12:25

PC Close Date & Time

26 AUG 2020 14:55

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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

26 AUG 2020 19:00

PC Open Date & Time

26 AUG 2020 15:50

PC Close Date & Time

27 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

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

27 AUG 2020 14:14

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

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

28 AUG 2020 18:03

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

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

29 AUG 2020 18:05

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

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

30 AUG 2020 19:42

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

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

31 AUG 2020 15:27

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

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

01 SEP 2020 17:17

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 12:38
PC Open Date & Time	26 AUG 2020 12:25
PC Close Date & Time	26 AUG 2020 14:55

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 19:01
PC Open Date & Time	26 AUG 2020 15:50
PC Close Date & Time	27 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	27 AUG 2020 14:15
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	28 AUG 2020 18:04
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	29 AUG 2020 18:05
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	30 AUG 2020 19:42
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	31 AUG 2020 15:28
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

Yes ☐	
PC Time stamp	01 SEP 2020 17:17
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3412013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

Was Contact Attempted?

Yes ☒

No ☐

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

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

Was Contact Attempted?

Yes ☒

No ☐

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

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

US3412013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

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.

US3412013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	24 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:09 (24 HR)
Collection date and time (derived)	24 SEP 2020 12:09

US3412013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	01 OCT 2020 15:53:07
Patient Cloud Open Date & Time	28 SEP 2020 00:01
Patient Cloud Close Date & Time	02 OCT 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 OCT 2020 18:04:30

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 OCT 2020 00:02:15

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 12:25:54

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 06:20:59

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 17:55:48

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 18:28:44

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2020 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐
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	22 NOV 2020 14:17:15
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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°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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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°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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3412013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

Was Contact Attempted?

Yes ☒

No ☐

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

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

US3412013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:50

Date of Contact	02 OCT 2020
Time of Contact	11:00
Date and Time of Contact (derived)	02 OCT 2020 11:00
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 ☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	02 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature	36.9 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	345 of 2284	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

	Severe	☒
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	349 of 2284	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

	Severe	☒
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	04 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	353 of 2284	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	357 of 2284	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	361 of 2284	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	365 of 2284	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☒

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	01 OCT 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	369 of 2284	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	373 of 2284	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	377 of 2284	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:50

Date of Visit	02 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	02 OCT 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:23:50

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:23:50

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 OCT 2020
Day 5	Yes	06 OCT 2020
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	02 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:25 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 11:25
Height (<i>xxx.x</i>)	167.5 cm
Weight (<i>xxx.x</i>)	87.3 kg
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	94 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3412013

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:23:50

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

02 OCT 2020

US3412013

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3412013

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

US3412013

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

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.

US3412013

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:23:50

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3412013

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:50

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

AEID	
Adverse event	UPPER RESPIRATORY INFECTION
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)	29 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	

v6.020 DTW (1102) 392 of 2284

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

AEID	USA-US061-2020-MRNA-1273-P30
	1000014
Adverse event	CATBITE
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)	20 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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)	22 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	1

v6.020 DTW (1102)

394 of 2284

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

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	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

SUBJECT NOTICED US THROUGH E-DIARY THAT SHE HAD CONTACT WITH A MEDICAL PROVIDER. SHE WENT TO SEE HER PCP ON 20-NOV-2020 TO FOLLOW UP ON HER PERSISTENT COUGH. HE ADVISED HER ON SOME OTC MEDICATIONS TO TRY. SHE HAS YET TO TRY ANY HE RECCOMENDED. ON FRIDAY ENTRY SHE WAS BIT BY HER CAT ON HER LEFT HAND. ON SATURDAY 21NOV2020 SHE WENT TO GOOD SAM ER WITH REDNESS, SWELLING, AND PAIN IN HER LEFT HAND. SHE WAS TOLD TO WATCH AND WAIT AND RETURN IF WORSENERD. SHE RETURNED TO GOOD SAM ER ON SUNDAY 22 NOV 2020 AND ADMITTED FOR A SEVERE INFECTION IN HER LEFT HAND DUE TO CATBITE. SHE HAS BEEN STARTED ON VANCOMYCIN IV AND IS WAITING FOR CONSULT FROM A HAND SURGEON THIS AFTERNOON. HER COUGH HAS ALSO WORSENERD TODAY AND SHE IS DISCUSSING IT WITH HER HOSPITALIST TODAY. SITE WILL CALL HER TOMORROW TO CHECK IN AND OBTAIN MORE INFORMATION.

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

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:50

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

Yes ☒

No ☐

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

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ☒
Indication	HTN
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

	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	☒

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	ATROVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HLD
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

	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	☒

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	GLIMEPIRIDE
Prophylaxis	Yes ☐ No ☒
Indication	T2DM
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

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 ☒

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	ESTRADIOL
Prophylaxis	Yes ☐ No ☒
Indication	POST-MENOPAUSE
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

	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	☒

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	OMEPRAZOLE
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

	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	☒

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	CLONAZEPAM
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

	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 2014
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	☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	MCLIZINE
Prophylaxis	Yes ☐ No ☒
Indication	VERTIGO
Dose per administration	25
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	FAMCICLOVIR
Prophylaxis	Yes ☐ No ☒
Indication	FEVER BLISTERS
Dose per administration	250
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

	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 2018
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	☒

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	MIDODRINE
Prophylaxis	Yes ☐ No ☒
Indication	DYSAUTONOMIA
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	JANUVIA
Prophylaxis	Yes ☐ No ☒
Indication	T2DM
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

	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	☒

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	VITAMIN D
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL SUPPLEMENT
Dose per administration	25
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

	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	☒

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	LYRICA
Prophylaxis	Yes ☐ No ☒
Indication	DYSAUTONOMIA
Dose per administration	300
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

	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 2008
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	☒

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	INVOCANA
Prophylaxis	Yes ☐ No ☒
Indication	DMT2
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

	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 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	☒

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	INJECTION SITE PAIN "SOLICITED EVENT"
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

	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 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	MUCINEX COUGH SYRUP
Prophylaxis	Yes ☐ No ☒
Indication	UPPER RESPIRATORY INFECTION AE
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	NONE
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	Q6HR / PRN
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

	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)		29 SEP 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

Name of Medication	ADVIL
Prophylaxis	Yes ☐ No ☒
Indication	UPPER RESPIRATORY INFECTION AE
Dose per administration	200
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 ☐

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

	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)		29 SEP 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:23:50

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3412013

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:23:50

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

US3412013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:23:50

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 ☐

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

SAEID	USA-US061-2020-MRNA-1273-P301000014
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)	1

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:50

SAEID	USA-US061-2020-MRNA-1273-P301000014
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)	1
Date of submission (Pre-filled from custom function)	24/NOV/2020 08:03
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

US3412013 (Prod: New Horizons Clinical Research)

US3412013

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:50

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:19
User entered 'US3412013'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:44:19

US3412013

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:00:42
User entered 'Yes (Y)'	Steven Anderson (b) (4)	29 Jul 2020 16:46:14

US3412013

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:00:42
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:44:20

US3412013

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:00:42
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	29 Jul 2020 16:46:14

US3412013

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	29 Jul 2020 16:46:14

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered (b) (6) 1962'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:44:21

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '58'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '58'	System	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered 'Female (F)'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '1'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered empty.	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:50

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:50

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:43
User entered '29 Jul 2020'	Steven Anderson (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '2020'	System	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:50

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered 'Amendment 1 (1)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered 'Yes (Y)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:50

If No, indicate reason for screen fail

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered empty.	Steven Anderson (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered empty.	Steven Anderson (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered 'No (N)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:44:20

US3412013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:04:35
User entered 'Yes (Y)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:04:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 16:00:46

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:50

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 16:08:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 16:08:07
Data point term sent to Coder	System	04 Aug 2020 16:07:19
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2010'	(b) (4), (b) (6)	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '2010'	System	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:50

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
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) (b) (4)	04 Aug 2020 16:08:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 16:08:07
Data point term sent to Coder	System	04 Aug 2020 16:07:19
User entered 'Hypertension'	(b) (4), (b) (6)	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2010'	(b) (4), (b) (6)	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '2010'	System	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:50

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
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) (b) (4)	04 Aug 2020 19:18:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:18:09
Data point term sent to Coder	System	04 Aug 2020 19:17:29
User entered 'GERD'	(b) (4), (b) (6)	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2010'	(b) (4), (b) (6)	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '2010'	System	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:50

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Please confirm' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:49:38
Query 'Please confirm' answered with 'confirming' (Site from CRA).	Jacob sekinger (b) (4)	03 Nov 2020 18:11:37
DataPoint Verified.	(b) (4)	03 Nov 2020 17:44:52
	(b) (4), (b) (6)	
User opened query 'Please confirm' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:43:25
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 17:43:17
	(b) (4), (b) (6)	
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)	03 Oct 2020 09:27:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 09:27:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:05:46
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)	04 Aug 2020 19:20:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Aug 2020 19:20:00
Data point term sent to Coder	System	04 Aug 2020 19:18:30
User entered 'Chronic Lower Back Pain'	(b) (4), (b) (6)	04 Aug 2020 19:17:31
	(b) (4), (b) (6)	

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2007'	(b) (4), (b) (6)	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '2007'	System	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:50

Condition

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 15:10:14
User closed query 'Please review source and confirm - Type II diabetes?' (Site from CRA).	(b) (4), (b) (6)	28 Sep 2020 15:10:11
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:52:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:52:38
Data point term sent to Coder	System	10 Sep 2020 15:51:59
Query 'Please review source and confirm - Type II diabetes?' answered with 'YES' (Site from CRA).	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:51:56
Coding entries removed.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:51:14
User entered 'DIABETES TYPE II' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:51:14
DataPoint Un-verified.	(b) (4), (b) (6)	25 Aug 2020 14:07:16
User opened query 'Please review source and confirm - Type II diabetes?' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 14:07:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type 1 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:20:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:20:02
Data point term sent to Coder	System	04 Aug 2020 19:19:32
User entered 'Diabetes Type 1'	(b) (4), (b) (6)	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2005'	(b) (4), (b) (6)	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '2005'	System	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:50

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:20:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:20:02
Data point term sent to Coder	System	04 Aug 2020 19:19:34
User entered 'Anxiety'	(b) (4), (b) (6)	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2010'	(b) (4), (b) (6)	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '2010'	System	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:50

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:20:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:20:02
Data point term sent to Coder	System	04 Aug 2020 19:19:31
User entered 'Vertigo'	(b) (4), (b) (6)	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2015'	(b) (4), (b) (6)	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '2015'	System	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:50

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Oral herpes, LLT: Fever blister - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 23:00:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 23:00:07
Data point term sent to Coder	System	04 Aug 2020 19:19:34
User entered 'Fever Blisters'	(b) (4), (b) (6)	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Un UNK 1965'	(b) (4), (b) (6)	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Jan 1965'	System	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '1965'	System	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:50

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 15:10:49
User closed query 'Please correct spelling Dysautonomia' (Site from CRA).	(b) (4), (b) (6)	28 Sep 2020 15:10:46
User coded data point as SOC: Nervous system disorders, HLGT: Neuromuscular disorders, HLT: Autonomic nervous system disorders, PT: Autonomic nervous system imbalance, LLT: Dysautonomia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:54:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:54:55
Query 'Please correct spelling Dysautonomia' answered with 'dysautonomia' (Site from CRA).	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:53:13
Data point term sent to Coder	System	10 Sep 2020 15:53:05
Data point term sent to Coder	System	10 Sep 2020 15:53:05
User closed query 'DM-Coding: Please update the term DYSACRINOMIA by providing further details for a more specific meaning/diagnosis.' (Site from System).	System	10 Sep 2020 15:53:05
Query 'DM-Coding: Please update the term DYSACRINOMIA by providing further details for a more specific meaning/diagnosis.' answered with 'dysautonomia' (Site from System).	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:53:05
User entered 'dysautonomia' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:52:58
DataPoint Un-verified.	(b) (4), (b) (6)	25 Aug 2020 14:16:55
User opened query 'Please correct spelling Dysautonomia' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 14:15:48
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User opened query 'DM-Coding: Please update the term DYSACRINOMIA by providing further details for a more specific meaning/diagnosis.' (Site from System).	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:54:09
Data point term sent to Coder	System	04 Aug 2020 19:19:34
User entered 'Dysacrinomia'	(b) (4), (b) (6)	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:44:40
DataPoint Un-verified.	Mylene Asmar-Rios	29 Sep 2020 21:24:02
	(b) (4)	
User entered 'UN UNK 2008' reason for change:	Mylene Asmar-Rios	29 Sep 2020 21:24:02
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2015'	(b) (4), (b) (6)	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	29 Sep 2020 21:24:02
User entered 'Jan 2015'	System	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '2008'	System	29 Sep 2020 21:24:02
User entered '2015'	System	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:50

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:44:52
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)	08 Oct 2020 22:42:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 22:42:53
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 14:58:58
User entered 'post menopausal'	Jacob sekinger (b) (4)	08 Oct 2020 14:58:08
	(b) (4)	

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:44:52
User entered 'un UNK 2008'	Jacob sekinger (b) (4)	08 Oct 2020 14:58:08
	(b) (4)	

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:44:52
User entered '0'	Jacob sekinger (b) (4)	08 Oct 2020 14:58:08
	(b) (4)	

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:44:52
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	08 Oct 2020 14:58:08
	(b) (4)	

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:44:52
User entered empty.	Jacob sekinger (b) (4)	08 Oct 2020 14:58:08
	(b) (4)	

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:44:52
User entered '0'	Jacob sekinger (b) (4)	08 Oct 2020 14:58:08
	(b) (4)	

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '2008'	System	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:17:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:17:24
User entered '29 Jul 2020'	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:17:31
User entered '12:05'	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:05'	System	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:17:42
User entered '167.5' cm	(b) (4), (b) (6)	04 Aug 2020 19:24:53
DataPoint set to visible.	System	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:17:44
User entered '87.6' kg	(b) (4), (b) (6)	04 Aug 2020 19:24:53
DataPoint set to visible.	System	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '31.22299'	System	16 Sep 2020 23:38:05
User entered '31.2'	System	04 Aug 2020 19:24:53
DataPoint set to visible.	System	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	04 Aug 2020 19:24:53
DataPoint set to visible.	System	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:48:10
	(b) (4)	
User entered '36.8' C	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:45:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 04:22:55
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Mylene Asmar-Rios	19 Aug 2020 16:48:19
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 16:48:10
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:48:10
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:48:10
User entered '82'	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:48:10
User entered '16'	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:48:10
User entered '128'	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:48:10
	(b) (4)	
User entered '76'	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:18:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:25:08

US3412013

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

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)	27 Aug 2020 13:35:12
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		26 Aug 2020 15:55:55
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:18:04
User entered '29 Jul 2020'	(b) (4), (b) (6)	04 Aug 2020 19:25:08

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered '29 Jul 2020'	(b) (4), (b) (6)	04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:50

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per CDML Response noted. However, the condition is not recorded on the Medical History CRF. Please update. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 12:29:25
Query 'Per CDML Response noted. However, the condition is not recorded on the Medical History CRF. Please update. ' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	08 Oct 2020 14:57:32
User opened query 'Per CDML Response noted. However, the condition is not recorded on the Medical History CRF. Please update. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 19:08:23
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)	07 Oct 2020 19:08:23
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 'ok' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Oct 2020 13:26:22
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)	04 Oct 2020 07:33:39
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:50

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:50

Date of surgery unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered 'un UNK 2008'	(b) (4), (b) (6)	04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:50

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:20
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:22
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:24
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:34
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:36
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:42
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:44
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:46
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered '1'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered '0'	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

[Other](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Oct 2020 12:14:04
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:50

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:45:23
DataPoint Un-verified.	Steven Anderson (b) (4)	02 Oct 2020 12:14:04
	(b) (4)	
User entered 'Socializes, shared apartment entrance, and lives in high risk county' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Oct 2020 12:14:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:21:01
User entered 'Yes (Y)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:31

US3412013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:21:01
User entered '29 Jul 2020'	Steven Anderson (b) (4)	29 Jul 2020 16:47:31

US3412013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:21:01
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:31

US3412013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	29 Jul 2020 16:47:31

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:36
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:44:34

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:36
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:14:30
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:14:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 16:44:34
User entered '142255' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:44:34

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	10 Sep 2020 15:57:11
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:36
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	29 Jul 2020 16:47:49
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:44:34

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:36
User entered 'No (N)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:49

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:36
User entered 'No (N)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:49

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:36
User entered 'No (N)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:49

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:50

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 15:11:25
User closed query 'Subject has Type II diabetes per source - please confirm and correct response to YES' (Site from CRA).	(b) (4), (b) (6)	28 Sep 2020 15:11:19
Query 'Subject has Type II diabetes per source - please confirm and correct response to YES' answered with 'YES' (Site from CRA).	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:57:18
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:57:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:57:11
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:36
User opened query 'Subject has Type II diabetes per source - please confirm and correct response to YES' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 14:29:22
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:49

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:50

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:36
User entered 'No (N)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:49

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:50

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:50

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:56
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:50

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:50

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:56
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:53:09
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '29 Jul 2020' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:53:09
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '12:05' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:53:09
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:05'	System	19 Aug 2020 16:53:09
User entered empty.	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '36.8' C reason for change: Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:53:09
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:53:09
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '82' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:53:09
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 16:53:09
User entered empty.	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '16' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:53:09
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 16:53:09
User entered empty.	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '128' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:53:09
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 16:53:09
User entered empty.	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '76' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 16:53:09
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 16:53:09
User entered empty.	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:50

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:50

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:56
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '29 Jul 2020'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User closed 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).	(b) (4), (b) (6)	17 Aug 2020 16:00:11
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, post dose vitals are > 30 min' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 19:22:02
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		04 Aug 2020 19:21:35
User entered '13:35'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 13:35'	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:46:58
User entered '97.3' F reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 15:59:59
	(b) (4)	
DataPoint Un-verified.	Mylene Asmar-Rios	10 Sep 2020 15:57:44
	(b) (4)	
User entered '97.8' F reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 15:57:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '97.3' F	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:46:58
User entered '75' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 15:59:59
	(b) (4)	
DataPoint Un-verified.	Mylene Asmar-Rios	10 Sep 2020 15:58:16
	(b) (4)	
User entered '84' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 15:58:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '75'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '18'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:46:58
User entered '125' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 15:59:59
	(b) (4)	
DataPoint Un-verified.	Mylene Asmar-Rios	10 Sep 2020 15:58:40
	(b) (4)	
User entered '128' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 15:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '125'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:46:58
User entered '70' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 15:59:59
	(b) (4)	
DataPoint Un-verified.	Mylene Asmar-Rios	10 Sep 2020 15:58:40
	(b) (4)	
User entered '72' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 15:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '70'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:04
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:22:19

US3412013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:04
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:22:19

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered 'Yes (Y)'	Steven Anderson (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

If No, reason not given

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered empty.	Steven Anderson (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered empty.	Steven Anderson (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered '29 Jul 2020'	Steven Anderson (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered '13:00'	Steven Anderson (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 13:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered 'ONCE'	System	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:23:23

US3412013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:56
User entered '29 Jul 2020'	(b) (4), (b) (6)	04 Aug 2020 19:23:23

US3412013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:56
User entered '12:25'	(b) (4), (b) (6)	04 Aug 2020 19:23:23

US3412013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:25'	System	04 Aug 2020 19:23:23

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:38:05
User entered '29 Jul 2020'	(b) (4), (b) (6)	04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:50

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:38:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:38:05
User entered '12:37'	(b) (4), (b) (6)	04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:37'	System	04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:50

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:38:05
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:38:05
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:38:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 19:22:26

US3412013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 19:22:26

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:38:55', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4e2c5d12-1a29-4464-b268-dcb9b9c3b432'	System	29 Jul 2020 17:39:41
User entered 'Yes (Y)'	System	29 Jul 2020 17:39:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:39:01', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4e2c5d12-1a29-4464-b268-dcb9b9c3b432'	System	29 Jul 2020 17:39:41
User entered '97.3'	System	29 Jul 2020 17:39:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:39:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4e2c5d12-1a29-4464-b268-dcb9b9c3b432'	System	29 Jul 2020 17:39:41
User entered 'No (N)'	System	29 Jul 2020 17:39:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:39:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4e2c5d12-1a29-4464-b268-dcb9b9c3b432'	System	29 Jul 2020 17:39:41
User entered '29 Jul 2020 13:39'	System	29 Jul 2020 17:39:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 13:20'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 15:50'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:05:06', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '39e31811-8381-41e0-af14-c20f7d5b3a5c'	System	30 Jul 2020 00:05:55
User entered 'Yes (Y)'	System	30 Jul 2020 00:05:55

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:05:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '39e31811-8381-41e0-af14-c20f7d5b3a5c'	System	30 Jul 2020 00:05:55
User entered '98.2'	System	30 Jul 2020 00:05:55

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:05:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '39e31811-8381-41e0-af14-c20f7d5b3a5c'	System	30 Jul 2020 00:05:55
User entered 'No (N)'	System	30 Jul 2020 00:05:55

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:05:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '39e31811-8381-41e0-af14-c20f7d5b3a5c'	System	30 Jul 2020 00:05:55
User entered '29 Jul 2020 20:05'	System	30 Jul 2020 00:05:55

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 16:45'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 2'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:36:43', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f66c9578-0201-4d3d-b863-0e88ef402d56'	System	30 Jul 2020 16:37:18
User entered 'Yes (Y)'	System	30 Jul 2020 16:37:18

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:36:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f66c9578-0201-4d3d-b863-0e88ef402d56'	System	30 Jul 2020 16:37:18
User entered '97.3'	System	30 Jul 2020 16:37:18

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:36:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f66c9578-0201-4d3d-b863-0e88ef402d56'	System	30 Jul 2020 16:37:18
User entered 'No (N)'	System	30 Jul 2020 16:37:18

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:37:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f66c9578-0201-4d3d-b863-0e88ef402d56'	System	30 Jul 2020 16:37:18
User entered '30 Jul 2020 12:37'	System	30 Jul 2020 16:37:18

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 3'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:55:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '82c3d665-24e0-4b63-a4fb-92a398bdf4e0'	System	31 Jul 2020 16:55:52
User entered 'Yes (Y)'	System	31 Jul 2020 16:55:52

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:55:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '82c3d665-24e0-4b63-a4fb-92a398bdf4e0'	System	31 Jul 2020 16:55:52
User entered '98.1'	System	31 Jul 2020 16:55:52

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:55:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '82c3d665-24e0-4b63-a4fb-92a398bdf4e0'	System	31 Jul 2020 16:55:52
User entered 'No (N)'	System	31 Jul 2020 16:55:52

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:55:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '82c3d665-24e0-4b63-a4fb-92a398bdf4e0'	System	31 Jul 2020 16:55:52
User entered '31 Jul 2020 12:55'	System	31 Jul 2020 16:55:52

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 4'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:30', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3db054d6-4b4a-44c9-8cd2-edcc1716e86e'	System	01 Aug 2020 22:25:34
User entered 'Yes (Y)'	System	01 Aug 2020 22:25:34

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3db054d6-4b4a-44c9-8cd2-edcc1716e86e'	System	01 Aug 2020 22:25:34
User entered '97.8'	System	01 Aug 2020 22:25:34

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:23', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3db054d6-4b4a-44c9-8cd2-edcc1716e86e'	System	01 Aug 2020 22:25:34
User entered 'No (N)'	System	01 Aug 2020 22:25:34

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:45', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3db054d6-4b4a-44c9-8cd2-edcc1716e86e'	System	01 Aug 2020 22:25:34
User entered '01 Aug 2020 18:24'	System	01 Aug 2020 22:25:34

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 5'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:02:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e9ed12f6-fddf-4d15-8713-71d859e54c84'	System	02 Aug 2020 17:03:10
User entered 'Yes (Y)'	System	02 Aug 2020 17:03:10

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:02:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e9ed12f6-fddf-4d15-8713-71d859e54c84'	System	02 Aug 2020 17:03:10
User entered '97.6'	System	02 Aug 2020 17:03:10

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:02:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e9ed12f6-fddf-4d15-8713-71d859e54c84'	System	02 Aug 2020 17:03:10
User entered 'No (N)'	System	02 Aug 2020 17:03:10

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e9ed12f6-fddf-4d15-8713-71d859e54c84'	System	02 Aug 2020 17:03:10
User entered '02 Aug 2020 13:03'	System	02 Aug 2020 17:03:10

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 6'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T12:37:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd31ea303-1166-447c-8ed4-36aa309e3cfc'	System	03 Aug 2020 16:38:41
User entered 'Yes (Y)'	System	03 Aug 2020 16:38:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T12:37:55', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd31ea303-1166-447c-8ed4-36aa309e3cfc'	System	03 Aug 2020 16:38:41
User entered '97.8'	System	03 Aug 2020 16:38:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T12:37:59', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd31ea303-1166-447c-8ed4-36aa309e3cfc'	System	03 Aug 2020 16:38:41
User entered 'No (N)'	System	03 Aug 2020 16:38:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T12:38:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd31ea303-1166-447c-8ed4-36aa309e3cfc'	System	03 Aug 2020 16:38:41
User entered '03 Aug 2020 12:38'	System	03 Aug 2020 16:38:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 7'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:29:57', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '882b1bff-b13e-4767-bb7b-510910f79397'	System	05 Aug 2020 15:30:19
User entered 'Yes (Y)'	System	05 Aug 2020 15:30:19

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:03', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '882b1bff-b13e-4767-bb7b-510910f79397'	System	05 Aug 2020 15:30:19
User entered '97.7'	System	05 Aug 2020 15:30:19

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:06', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '882b1bff-b13e-4767-bb7b-510910f79397'	System	05 Aug 2020 15:30:19
User entered 'No (N)'	System	05 Aug 2020 15:30:19

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:11', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '882b1bff-b13e-4767-bb7b-510910f79397'	System	05 Aug 2020 15:30:19
User entered '05 Aug 2020 11:30'	System	05 Aug 2020 15:30:19

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-29T13:41:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0bc02c18-93d4-4b3d-bf45-73b05f84b419'	System	29 Jul 2020 17:42:34
User entered 'Does not interfere with activity (2)'	System	29 Jul 2020 17:42:34

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:41:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0bc02c18-93d4-4b3d-bf45-73b05f84b419'	System	29 Jul 2020 17:42:34
User entered 'No (N)'	System	29 Jul 2020 17:42:34

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:41:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0bc02c18-93d4-4b3d-bf45-73b05f84b419'	System	29 Jul 2020 17:42:34
User entered 'No (N)'	System	29 Jul 2020 17:42:34

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-29T13:42:18', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0bc02c18-93d4-4b3d-bf45-73b05f84b419'	System	29 Jul 2020 17:42:34
User entered 'Does not interfere with activity (2)'	System	29 Jul 2020 17:42:34

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:42:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0bc02c18-93d4-4b3d-bf45-73b05f84b419'	System	29 Jul 2020 17:42:34
User entered '29 Jul 2020 13:42'	System	29 Jul 2020 17:42:34

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 13:20'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 15:50'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-29T20:02:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '809addc8-7b98-477b-a86e-5bbf70ea7890'	System	30 Jul 2020 00:03:18
User entered 'Does not interfere with activity (2)'	System	30 Jul 2020 00:03:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:02:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '809addc8-7b98-477b-a86e-5bbf70ea7890'	System	30 Jul 2020 00:03:18
User entered 'No (N)'	System	30 Jul 2020 00:03:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:02:59', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '809addc8-7b98-477b-a86e-5bbf70ea7890'	System	30 Jul 2020 00:03:18
User entered 'No (N)'	System	30 Jul 2020 00:03:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:03', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '809addc8-7b98-477b-a86e-5bbf70ea7890'	System	30 Jul 2020 00:03:18
User entered 'None (1)'	System	30 Jul 2020 00:03:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '809addc8-7b98-477b-a86e-5bbf70ea7890'	System	30 Jul 2020 00:03:18
User entered '29 Jul 2020 20:03'	System	30 Jul 2020 00:03:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 16:45'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 2'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-30T12:37:43', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd775eaf6-a22c-446c-9bb8-73aa29698553'	System	30 Jul 2020 16:38:11
User entered 'Does not interfere with activity (2)'	System	30 Jul 2020 16:38:11

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:37:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd775eaf6-a22c-446c-9bb8-73aa29698553'	System	30 Jul 2020 16:38:11
User entered 'No (N)'	System	30 Jul 2020 16:38:11

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:37:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd775eaf6-a22c-446c-9bb8-73aa29698553'	System	30 Jul 2020 16:38:11
User entered 'No (N)'	System	30 Jul 2020 16:38:11

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-30T12:37:57', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd775eaf6-a22c-446c-9bb8-73aa29698553'	System	30 Jul 2020 16:38:11
User entered 'None (1)'	System	30 Jul 2020 16:38:11

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd775eaf6-a22c-446c-9bb8-73aa29698553'	System	30 Jul 2020 16:38:11
User entered '30 Jul 2020 12:38'	System	30 Jul 2020 16:38:11

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 3'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-31T12:55:57', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1e2ee076-c617-4ac3-802b-fbad760242af'	System	31 Jul 2020 16:56:18
User entered 'Does not interfere with activity (2)'	System	31 Jul 2020 16:56:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1e2ee076-c617-4ac3-802b-fbad760242af'	System	31 Jul 2020 16:56:18
User entered 'No (N)'	System	31 Jul 2020 16:56:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:03', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1e2ee076-c617-4ac3-802b-fbad760242af'	System	31 Jul 2020 16:56:18
User entered 'No (N)'	System	31 Jul 2020 16:56:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1e2ee076-c617-4ac3-802b-fbad760242af'	System	31 Jul 2020 16:56:18
User entered 'None (1)'	System	31 Jul 2020 16:56:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:13', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1e2ee076-c617-4ac3-802b-fbad760242af'	System	31 Jul 2020 16:56:18
User entered '31 Jul 2020 12:56'	System	31 Jul 2020 16:56:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 4'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:50', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '7f26ece9-a9fd-46b2-b792-bf664b470686'	System	01 Aug 2020 22:26:00
User entered 'None (1)'	System	01 Aug 2020 22:26:00

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '7f26ece9-a9fd-46b2-b792-bf664b470686'	System	01 Aug 2020 22:26:00
User entered 'No (N)'	System	01 Aug 2020 22:26:00

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '7f26ece9-a9fd-46b2-b792-bf664b470686'	System	01 Aug 2020 22:26:00
User entered 'No (N)'	System	01 Aug 2020 22:26:00

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:01', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '7f26ece9-a9fd-46b2-b792-bf664b470686'	System	01 Aug 2020 22:26:00
User entered 'None (1)'	System	01 Aug 2020 22:26:00

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:06', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '7f26ece9-a9fd-46b2-b792-bf664b470686'	System	01 Aug 2020 22:26:00
User entered '01 Aug 2020 18:25'	System	01 Aug 2020 22:26:00

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 5'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:15', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f919fd9a-eae5-4bbd-863c-7de89f57fb91'	System	02 Aug 2020 17:03:38
User entered 'None (1)'	System	02 Aug 2020 17:03:38

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f919fd9a-eae5-4bbd-863c-7de89f57fb91'	System	02 Aug 2020 17:03:38
User entered 'No (N)'	System	02 Aug 2020 17:03:38

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:23', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f919fd9a-eae5-4bbd-863c-7de89f57fb91'	System	02 Aug 2020 17:03:38
User entered 'No (N)'	System	02 Aug 2020 17:03:38

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f919fd9a-eae5-4bbd-863c-7de89f57fb91'	System	02 Aug 2020 17:03:38
User entered 'None (1)'	System	02 Aug 2020 17:03:38

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f919fd9a-eae5-4bbd-863c-7de89f57fb91'	System	02 Aug 2020 17:03:38
User entered '02 Aug 2020 13:03'	System	02 Aug 2020 17:03:38

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 6'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-03T14:44:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '062f963d-4203-48f9-86f6-773c6563f72e'	System	03 Aug 2020 18:45:09
User entered 'None (1)'	System	03 Aug 2020 18:45:09

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:44:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '062f963d-4203-48f9-86f6-773c6563f72e'	System	03 Aug 2020 18:45:09
User entered 'No (N)'	System	03 Aug 2020 18:45:09

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:44:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '062f963d-4203-48f9-86f6-773c6563f72e'	System	03 Aug 2020 18:45:09
User entered 'No (N)'	System	03 Aug 2020 18:45:09

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '062f963d-4203-48f9-86f6-773c6563f72e'	System	03 Aug 2020 18:45:09
User entered 'None (1)'	System	03 Aug 2020 18:45:09

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '062f963d-4203-48f9-86f6-773c6563f72e'	System	03 Aug 2020 18:45:09
User entered '03 Aug 2020 14:45'	System	03 Aug 2020 18:45:09

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 7'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fa76671a-7924-4281-9081-5173cc8ad7cb'	System	05 Aug 2020 15:30:36
User entered 'None (1)'	System	05 Aug 2020 15:30:36

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fa76671a-7924-4281-9081-5173cc8ad7cb'	System	05 Aug 2020 15:30:36
User entered 'No (N)'	System	05 Aug 2020 15:30:36

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:23', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fa76671a-7924-4281-9081-5173cc8ad7cb'	System	05 Aug 2020 15:30:36
User entered 'No (N)'	System	05 Aug 2020 15:30:36

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:28', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fa76671a-7924-4281-9081-5173cc8ad7cb'	System	05 Aug 2020 15:30:36
User entered 'None (1)'	System	05 Aug 2020 15:30:36

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fa76671a-7924-4281-9081-5173cc8ad7cb'	System	05 Aug 2020 15:30:36
User entered '05 Aug 2020 11:30'	System	05 Aug 2020 15:30:36

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:16', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:18', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:21', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:28', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'No (N)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered '29 Jul 2020 13:43'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 13:20'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 15:50'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:31', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'No (N)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered '29 Jul 2020 20:03'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 16:45'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 2'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:13', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:16', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'No (N)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:50', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered '30 Jul 2020 12:38'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 3'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:19', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:36', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:47', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'No (N)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:57:01', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered '31 Jul 2020 12:57'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 4'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:13', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:18', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:21', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:25', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'No (N)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:41', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered '01 Aug 2020 18:25'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 5'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:52', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:55', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:04:01', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-02T13:04:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'No (N)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:04:12', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered '02 Aug 2020 13:04'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 6'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:16', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:23', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:26', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:30', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'No (N)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered '03 Aug 2020 14:45'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 7'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:47', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:50', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:52', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:55', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'No (N)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:59', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered '05 Aug 2020 11:30'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:41:42
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Aug 2020 22:26:39

US3412013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:41:42
User entered '05 Aug 2020'	Steven Anderson (b) (4)	05 Aug 2020 22:26:39

US3412013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:41:42
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	05 Aug 2020 22:26:39

US3412013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:41:42
User entered empty.	Steven Anderson (b) (4)	05 Aug 2020 22:26:39

US3412013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:42:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Aug 2020 22:26:44

US3412013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 22:26:44

US3412013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:42:32
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 14:08:21

US3412013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:42:32
User entered '12 Aug 2020'	Steven Anderson (b) (4)	17 Aug 2020 14:08:21

US3412013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:42:32
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	17 Aug 2020 14:08:21

US3412013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:42:32
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 14:08:21

US3412013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:42:37
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 14:08:30

US3412013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 14:08:30

US3412013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:42:48
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Aug 2020 22:31:12

US3412013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:42:48
User entered '19 Aug 2020'	Steven Anderson (b) (4)	19 Aug 2020 22:31:12

US3412013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:42:48
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	19 Aug 2020 22:31:12

US3412013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:42:48
User entered empty.	Steven Anderson (b) (4)	19 Aug 2020 22:31:12

US3412013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:42:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Aug 2020 22:31:18

US3412013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 22:31:18

US3412013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:28:24
User entered 'Yes (Y)'	Steven Anderson (b) (4)	26 Aug 2020 15:55:55

US3412013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:28:24
User entered '26 Aug 2020'	Steven Anderson (b) (4)	26 Aug 2020 15:55:55

US3412013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:28:24
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	26 Aug 2020 15:55:55

US3412013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	26 Aug 2020 15:55:55

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:35:58
User entered 'Yes (Y)'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:35:59
User entered '26 Aug 2020'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:36:00
User entered '11:06'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:06'	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:36:05
User entered '36.9' C	Steven Anderson (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:36:08
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:36:14
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:36:12
User entered '90'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:36:16
User entered '18'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:36:18
User entered '115'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:36:20
User entered '60'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:20
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 16:04:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 16:04:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:04:16
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:56:45
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '26 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 16:04:16
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '12:35' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 16:04:16
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:35'	System	10 Sep 2020 16:04:16
User entered empty.	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '97.8' F reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 16:04:16
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 16:04:16
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '84' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 16:04:16
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 16:04:16
User entered empty.	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '18' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 16:04:16
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 16:04:16
User entered empty.	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '128' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 16:04:16
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 16:04:16
User entered empty.	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '72' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 16:04:16
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 16:04:16
User entered empty.	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:13
User entered 'Yes (Y)'	Steven Anderson (b) (4)	26 Aug 2020 15:57:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:13
User entered '26 Aug 2020'	Steven Anderson (b) (4)	26 Aug 2020 15:57:00
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

If No, reason not given

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 16:09:42
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 16:09:42
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered '26 Aug 2020'	Steven Anderson (b) (4)	26 Aug 2020 16:09:42
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered '12:05'	Steven Anderson (b) (4)	26 Aug 2020 16:09:42
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:05'	System	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	26 Aug 2020 16:09:42
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered 'ONCE'	System	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:54
User entered 'Yes (Y)'	Steven Anderson (b) (4)	26 Aug 2020 15:57:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:54
User entered '26 Aug 2020'	Steven Anderson (b) (4)	26 Aug 2020 15:57:42
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:54
User entered '11:40'	Steven Anderson (b) (4)	26 Aug 2020 15:57:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:40'	System	26 Aug 2020 15:57:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:47:38
User entered '26 Aug 2020'	Mylene Asmar-Rios	10 Sep 2020 16:07:00
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:50

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:47:38
User entered 'Yes (Y)'	Mylene Asmar-Rios	10 Sep 2020 16:07:00
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:47:38
User entered '11:49'	Mylene Asmar-Rios	10 Sep 2020 16:07:00
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:49'	System	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:50

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:47:38
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 16:07:00
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:47:38
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 16:07:00
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:38:16
User entered 'Yes (Y)'	Steven Anderson (b) (4)	26 Aug 2020 15:57:47

US3412013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 15:57:47

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:36:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '70db97fc-dc0f-4a11-bb3e-051581546043'	System	26 Aug 2020 16:37:25
User entered 'Yes (Y)'	System	26 Aug 2020 16:37:25

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '70db97fc-dc0f-4a11-bb3e-051581546043'	System	26 Aug 2020 16:37:25
User entered '97.8'	System	26 Aug 2020 16:37:25

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '70db97fc-dc0f-4a11-bb3e-051581546043'	System	26 Aug 2020 16:37:25
User entered 'No (N)'	System	26 Aug 2020 16:37:25

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:21', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '70db97fc-dc0f-4a11-bb3e-051581546043'	System	26 Aug 2020 16:37:25
User entered '26 Aug 2020 12:37'	System	26 Aug 2020 16:37:25

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:25'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 14:55'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T18:59:26', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '994f1c89-8080-4c70-b5dd-9e1c92cca37f'	System	26 Aug 2020 22:59:51
User entered 'Yes (Y)'	System	26 Aug 2020 22:59:51

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T18:59:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '994f1c89-8080-4c70-b5dd-9e1c92cca37f'	System	26 Aug 2020 22:59:51
User entered '97.9'	System	26 Aug 2020 22:59:51

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T18:59:41', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '994f1c89-8080-4c70-b5dd-9e1c92cca37f'	System	26 Aug 2020 22:59:51
User entered 'No (N)'	System	26 Aug 2020 22:59:51

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T18:59:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '994f1c89-8080-4c70-b5dd-9e1c92cca37f'	System	26 Aug 2020 22:59:51
User entered '26 Aug 2020 18:59'	System	26 Aug 2020 22:59:51

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:50'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 2'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:12:52', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8'	System	27 Aug 2020 18:13:36
User entered 'Yes (Y)'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:13:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8'	System	27 Aug 2020 18:13:36
User entered '100.2'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:13:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8'	System	27 Aug 2020 18:13:36
User entered 'Yes (Y)'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

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 'spoke to subject' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 10:34:23
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).	(b) (4), (b) (6)	02 Sep 2020 21:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:13:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8'	System	27 Aug 2020 18:13:36
User entered '1'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:13:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8' User entered '0'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:13:30', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8'	System	27 Aug 2020 18:13:36
User entered '27 Aug 2020 14:13'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 3'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:02:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '8b483141-94ed-465a-aa92-50d9466bb4f3'	System	28 Aug 2020 22:03:17
User entered 'Yes (Y)'	System	28 Aug 2020 22:03:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:06', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '8b483141-94ed-465a-aa92-50d9466bb4f3'	System	28 Aug 2020 22:03:17
User entered '98.8'	System	28 Aug 2020 22:03:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '8b483141-94ed-465a-aa92-50d9466bb4f3'	System	28 Aug 2020 22:03:17
User entered 'No (N)'	System	28 Aug 2020 22:03:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '8b483141-94ed-465a-aa92-50d9466bb4f3'	System	28 Aug 2020 22:03:17
User entered '28 Aug 2020 18:03'	System	28 Aug 2020 22:03:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 4'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:04:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3776e44c-c924-4878-8415-22659ee923b4'	System	29 Aug 2020 22:05:02
User entered 'Yes (Y)'	System	29 Aug 2020 22:05:02

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:04:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3776e44c-c924-4878-8415-22659ee923b4'	System	29 Aug 2020 22:05:02
User entered '97.7'	System	29 Aug 2020 22:05:02

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:04:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3776e44c-c924-4878-8415-22659ee923b4'	System	29 Aug 2020 22:05:02
User entered 'No (N)'	System	29 Aug 2020 22:05:02

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:04:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3776e44c-c924-4878-8415-22659ee923b4'	System	29 Aug 2020 22:05:02
User entered '29 Aug 2020 18:04'	System	29 Aug 2020 22:05:02

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 5'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:41:39', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd72324f5-d9d5-4242-a7f3-0a30d60dc971'	System	30 Aug 2020 23:42:01
User entered 'Yes (Y)'	System	30 Aug 2020 23:42:01

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:41:50', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd72324f5-d9d5-4242-a7f3-0a30d60dc971'	System	30 Aug 2020 23:42:01
User entered '97.6'	System	30 Aug 2020 23:42:01

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:41:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd72324f5-d9d5-4242-a7f3-0a30d60dc971'	System	30 Aug 2020 23:42:01
User entered 'No (N)'	System	30 Aug 2020 23:42:01

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:41:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd72324f5-d9d5-4242-a7f3-0a30d60dc971'	System	30 Aug 2020 23:42:01
User entered '30 Aug 2020 19:41'	System	30 Aug 2020 23:42:01

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 6'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f2346526-8092-4460-b932-532ec2439888'	System	31 Aug 2020 19:31:17
User entered 'Yes (Y)'	System	31 Aug 2020 19:31:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:24', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f2346526-8092-4460-b932-532ec2439888'	System	31 Aug 2020 19:31:17
User entered '97.9'	System	31 Aug 2020 19:31:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:28', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f2346526-8092-4460-b932-532ec2439888'	System	31 Aug 2020 19:31:17
User entered 'No (N)'	System	31 Aug 2020 19:31:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f2346526-8092-4460-b932-532ec2439888'	System	31 Aug 2020 19:31:17
User entered '31 Aug 2020 15:27'	System	31 Aug 2020 19:31:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 7'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '65b7bc5e-9c1c-4af6-9b77-51f722ace173'	System	01 Sep 2020 21:16:48
User entered 'Yes (Y)'	System	01 Sep 2020 21:16:48

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:36', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '65b7bc5e-9c1c-4af6-9b77-51f722ace173'	System	01 Sep 2020 21:16:48
User entered '98.2'	System	01 Sep 2020 21:16:48

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '65b7bc5e-9c1c-4af6-9b77-51f722ace173'	System	01 Sep 2020 21:16:48
User entered 'No (N)'	System	01 Sep 2020 21:16:48

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '65b7bc5e-9c1c-4af6-9b77-51f722ace173'	System	01 Sep 2020 21:16:48
User entered '01 Sep 2020 17:16'	System	01 Sep 2020 21:16:48

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '25fc8693-6c03-4877-9ecf-5875baef0cf2'	System	26 Aug 2020 16:37:47
User entered 'None (1)'	System	26 Aug 2020 16:37:47

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '25fc8693-6c03-4877-9ecf-5875baef0cf2'	System	26 Aug 2020 16:37:47
User entered 'No (N)'	System	26 Aug 2020 16:37:47

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '25fc8693-6c03-4877-9ecf-5875baef0cf2'	System	26 Aug 2020 16:37:47
User entered 'No (N)'	System	26 Aug 2020 16:37:47

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '25fc8693-6c03-4877-9ecf-5875baef0cf2'	System	26 Aug 2020 16:37:47
User entered 'None (1)'	System	26 Aug 2020 16:37:47

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '25fc8693-6c03-4877-9ecf-5875baef0cf2'	System	26 Aug 2020 16:37:47
User entered '26 Aug 2020 12:37'	System	26 Aug 2020 16:37:47

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:25'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 14:55'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:11', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2d327a8b-749b-416c-8501-ebf7f5ae4d2c'	System	26 Aug 2020 23:00:32
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 23:00:32

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2d327a8b-749b-416c-8501-ebf7f5ae4d2c'	System	26 Aug 2020 23:00:32
User entered 'No (N)'	System	26 Aug 2020 23:00:32

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2d327a8b-749b-416c-8501-ebf7f5ae4d2c'	System	26 Aug 2020 23:00:32
User entered 'No (N)'	System	26 Aug 2020 23:00:32

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2d327a8b-749b-416c-8501-ebf7f5ae4d2c'	System	26 Aug 2020 23:00:32
User entered 'None (1)'	System	26 Aug 2020 23:00:32

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2d327a8b-749b-416c-8501-ebf7f5ae4d2c'	System	26 Aug 2020 23:00:32
User entered '26 Aug 2020 19:00'	System	26 Aug 2020 23:00:32

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:50'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 2'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:04', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e11da5d2-11e7-4557-be4c-bbf8fb1ae0e2'	System	27 Aug 2020 18:14:25
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 18:14:25

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e11da5d2-11e7-4557-be4c-bbf8fb1ae0e2'	System	27 Aug 2020 18:14:25
User entered 'No (N)'	System	27 Aug 2020 18:14:25

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:11', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e11da5d2-11e7-4557-be4c-bbf8fb1ae0e2'	System	27 Aug 2020 18:14:25
User entered 'No (N)'	System	27 Aug 2020 18:14:25

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e11da5d2-11e7-4557-be4c-bbf8fb1ae0e2'	System	27 Aug 2020 18:14:25
User entered 'None (1)'	System	27 Aug 2020 18:14:25

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:21', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e11da5d2-11e7-4557-be4c-bbf8fb1ae0e2'	System	27 Aug 2020 18:14:25
User entered '27 Aug 2020 14:14'	System	27 Aug 2020 18:14:25

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 3'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'dc927a67-adb9-4f8a-ae9a-3c10a1d12c2f'	System	28 Aug 2020 22:03:41
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 22:03:41

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:23', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'dc927a67-adb9-4f8a-ae9a-3c10a1d12c2f'	System	28 Aug 2020 22:03:41
User entered 'No (N)'	System	28 Aug 2020 22:03:41

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:25', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'dc927a67-adb9-4f8a-ae9a-3c10a1d12c2f'	System	28 Aug 2020 22:03:41
User entered 'No (N)'	System	28 Aug 2020 22:03:41

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:30', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'dc927a67-adb9-4f8a-ae9a-3c10a1d12c2f'	System	28 Aug 2020 22:03:41
User entered 'None (1)'	System	28 Aug 2020 22:03:41

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:36', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'dc927a67-adb9-4f8a-ae9a-3c10a1d12c2f'	System	28 Aug 2020 22:03:41
User entered '28 Aug 2020 18:03'	System	28 Aug 2020 22:03:41

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 4'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:04', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ab69582c-1269-4280-a39c-5793fc904313'	System	29 Aug 2020 22:05:20
User entered 'None (1)'	System	29 Aug 2020 22:05:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ab69582c-1269-4280-a39c-5793fc904313'	System	29 Aug 2020 22:05:20
User entered 'No (N)'	System	29 Aug 2020 22:05:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ab69582c-1269-4280-a39c-5793fc904313'	System	29 Aug 2020 22:05:20
User entered 'No (N)'	System	29 Aug 2020 22:05:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:13', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ab69582c-1269-4280-a39c-5793fc904313'	System	29 Aug 2020 22:05:20
User entered 'None (1)'	System	29 Aug 2020 22:05:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ab69582c-1269-4280-a39c-5793fc904313'	System	29 Aug 2020 22:05:20
User entered '29 Aug 2020 18:05'	System	29 Aug 2020 22:05:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 5'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:01', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '77a84680-b8c9-40bc-84d3-19462634bc8b'	System	30 Aug 2020 23:42:20
User entered 'None (1)'	System	30 Aug 2020 23:42:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:06', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '77a84680-b8c9-40bc-84d3-19462634bc8b'	System	30 Aug 2020 23:42:20
User entered 'No (N)'	System	30 Aug 2020 23:42:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '77a84680-b8c9-40bc-84d3-19462634bc8b'	System	30 Aug 2020 23:42:20
User entered 'No (N)'	System	30 Aug 2020 23:42:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:12', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '77a84680-b8c9-40bc-84d3-19462634bc8b'	System	30 Aug 2020 23:42:20
User entered 'None (1)'	System	30 Aug 2020 23:42:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:15', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '77a84680-b8c9-40bc-84d3-19462634bc8b'	System	30 Aug 2020 23:42:20
User entered '30 Aug 2020 19:42'	System	30 Aug 2020 23:42:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 6'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fff44811-320f-4df0-b7c7-2c7950e7a175'	System	31 Aug 2020 19:31:23
User entered 'None (1)'	System	31 Aug 2020 19:31:23

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fff44811-320f-4df0-b7c7-2c7950e7a175'	System	31 Aug 2020 19:31:23
User entered 'No (N)'	System	31 Aug 2020 19:31:23

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:45', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fff44811-320f-4df0-b7c7-2c7950e7a175'	System	31 Aug 2020 19:31:23
User entered 'No (N)'	System	31 Aug 2020 19:31:23

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fff44811-320f-4df0-b7c7-2c7950e7a175'	System	31 Aug 2020 19:31:23
User entered 'None (1)'	System	31 Aug 2020 19:31:23

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:52', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fff44811-320f-4df0-b7c7-2c7950e7a175'	System	31 Aug 2020 19:31:23
User entered '31 Aug 2020 15:27'	System	31 Aug 2020 19:31:23

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 7'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5ec26aac-3b83-4e2d-985e-73073286fdfa'	System	01 Sep 2020 21:17:10
User entered 'None (1)'	System	01 Sep 2020 21:17:10

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5ec26aac-3b83-4e2d-985e-73073286fdfa'	System	01 Sep 2020 21:17:10
User entered 'No (N)'	System	01 Sep 2020 21:17:10

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5ec26aac-3b83-4e2d-985e-73073286fdfa'	System	01 Sep 2020 21:17:10
User entered 'No (N)'	System	01 Sep 2020 21:17:10

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5ec26aac-3b83-4e2d-985e-73073286fdfa'	System	01 Sep 2020 21:17:10
User entered 'None (1)'	System	01 Sep 2020 21:17:10

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:04', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5ec26aac-3b83-4e2d-985e-73073286fdfa'	System	01 Sep 2020 21:17:10
User entered '01 Sep 2020 17:17'	System	01 Sep 2020 21:17:10

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:50', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:38:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:38:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:38:11', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-26T12:38:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'No (N)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:38:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered '26 Aug 2020 12:38'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:25'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 14:55'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:36', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:59', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-26T19:01:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'No (N)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:01:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered '26 Aug 2020 19:01'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:50'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 2'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'No interference with activity (1)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'Some interference with activity (2)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:45', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'Some interference with activity (2)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:52', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'Some interference with activity (2)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:15:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'None (0)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:15:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'No interference with activity (1)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-27T14:15:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'No (N)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:15:37', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered '27 Aug 2020 14:15'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 3'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcbaf4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcba4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcbaf4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcbaf4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcba4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcbaf4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-28T18:04:02', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcbaf4f'	System	28 Aug 2020 22:04:11
User entered 'No (N)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:04:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcbaf4f'	System	28 Aug 2020 22:04:11
User entered '28 Aug 2020 18:04'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 4'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:25', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:31', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:36', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:41', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'No (N)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:45', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered '29 Aug 2020 18:05'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 5'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:25', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:31', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'No (N)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered '30 Aug 2020 19:42'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 6'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:57', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:02', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:08', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:13', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:16', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'No (N)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:25', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered '31 Aug 2020 15:28'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 7'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:12', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:19', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:24', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'No (N)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:28', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered '01 Sep 2020 17:17'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:42:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 21:14:45

US3412013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:42:34
User entered '02 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 21:14:45

US3412013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:42:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Sep 2020 21:14:45

US3412013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:42:34
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 21:14:45

US3412013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:42:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 21:14:51

US3412013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:14:51

US3412013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:39:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Sep 2020 19:49:42
	(b) (4)	

US3412013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:39:39
User entered '9 Sep 2020'	Mason Urban (b) (4)	09 Sep 2020 19:49:42
	(b) (4)	

US3412013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:39:39
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	09 Sep 2020 19:49:42
	(b) (4)	

US3412013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:39:39
User entered empty.	Mason Urban (b) (4)	09 Sep 2020 19:49:42
	(b) (4)	

US3412013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:39:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Sep 2020 19:50:01
	(b) (4)	

US3412013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 19:50:01

US3412013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:40:01
User entered 'Yes (Y)'	Mason Urban (b) (4)	16 Sep 2020 20:15:47
	(b) (4)	

US3412013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:40:01
User entered '16 Sep 2020'	Mason Urban (b) (4)	16 Sep 2020 20:15:47
	(b) (4)	

US3412013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:40:01
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	16 Sep 2020 20:15:47
	(b) (4)	

US3412013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:40:01
User entered empty.	Mason Urban (b) (4)	16 Sep 2020 20:15:47
	(b) (4)	

US3412013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:40:04
User entered 'Yes (Y)'	Mason Urban (b) (4)	16 Sep 2020 20:15:38
	(b) (4)	

US3412013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 20:15:38

US3412013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:44
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	29 Sep 2020 16:10:42
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:44
User entered '24 Sep 2020'	Jacob sekinger (b) (4)	29 Sep 2020 16:10:42
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:44
User entered 'Clinic (Clinic)'	Jacob sekinger (b) (4)	29 Sep 2020 16:10:42
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	29 Sep 2020 16:10:42

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered 'No (N)'	Jacob sekinger (b) (4)	29 Sep 2020 16:11:16
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 16:11:16
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 16:11:16
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 16:11:16
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 16:11:16
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 16:11:16
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 16:11:16
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 16:11:16
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 16:11:16
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 16:11:16
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:43
DataPoint Un-verified.	Mylene Asmar-Rios	21 Oct 2020 17:07:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios	21 Oct 2020 17:07:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:43:17
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	29 Sep 2020 16:11:33
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:48:43
DataPoint Un-verified.	Mylene Asmar-Rios	21 Oct 2020 17:07:29
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios	21 Oct 2020 17:07:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:43:17
User entered '24 Sep 2020'	Jacob sekinger (b) (4)	29 Sep 2020 16:11:33
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 24Sep2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail' answered with 'Samples were shipped with AWB:910890148110 on 24SEP2020. We have a received a specimen received report indicating Immuno11-24 was received. ' (Site from DM).	Mylene Asmar-Rios (b) (4)	12 Oct 2020 13:26:58
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 24Sep2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 01:03:03
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:43:27
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:12:05

US3412013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:43:27
User entered '24 Sep 2020'	Jacob sekinger (b) (4)	29 Sep 2020 16:12:05
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:43:27
User entered '12:09'	Jacob sekinger (b) (4)	29 Sep 2020 16:12:05
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:09'	System	29 Sep 2020 16:12:05

US3412013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:43:55
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	29 Sep 2020 16:12:13
	(b) (4)	

US3412013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:12:13

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 64'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-10-01T15:51:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered 'Yes (Y)'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-10-01T15:51:57', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered 'No (N)'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:08', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered 'Yes (Y)'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Please 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 (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-10-01T15:53:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered 'No (N)'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:53:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '01 Oct 2020 15:53:07'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 71'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-10-07T18:04:21', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '955ead50-8394-4be1-ac54-9ea2521e49cb'	System	07 Oct 2020 22:04:36
User entered 'No (N)'	System	07 Oct 2020 22:04:36

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-10-07T18:04:24', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '955ead50-8394-4be1-ac54-9ea2521e49cb'	System	07 Oct 2020 22:04:36
User entered 'No (N)'	System	07 Oct 2020 22:04:36

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-07T18:04:30', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '955ead50-8394-4be1-ac54-9ea2521e49cb' User entered '07 Oct 2020 18:04:30'	System	07 Oct 2020 22:04:36
	System	07 Oct 2020 22:04:36

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 78'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-10-12T00:02:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6482ce6a-8574-4a74-ab2b-2fff392a8509'	System	12 Oct 2020 04:02:17
User entered 'No (N)'	System	12 Oct 2020 04:02:17

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-10-12T00:02:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6482ce6a-8574-4a74-ab2b-2fff392a8509'	System	12 Oct 2020 04:02:17
User entered 'No (N)'	System	12 Oct 2020 04:02:17

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-12T00:02:15', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6482ce6a-8574-4a74-ab2b-2fff392a8509'	System	12 Oct 2020 04:02:17
User entered '12 Oct 2020 00:02:15'	System	12 Oct 2020 04:02:17

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 92'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-10-26T12:25:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '33deb048-fb42-4792-9527-e52a316c63c3'	System	26 Oct 2020 16:26:00
User entered 'No (N)'	System	26 Oct 2020 16:26:00

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-10-26T12:25:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '33deb048-fb42-4792-9527-e52a316c63c3'	System	26 Oct 2020 16:26:00
User entered 'No (N)'	System	26 Oct 2020 16:26:00

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-26T12:25:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '33deb048-fb42-4792-9527-e52a316c63c3'	System	26 Oct 2020 16:26:00
User entered '26 Oct 2020 12:25:54'	System	26 Oct 2020 16:26:00

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 99'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-11-02T06:20:45', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5f79f44b-2be1-4c1a-8ce8-b1f97a605c7b'	System	02 Nov 2020 11:21:05
User entered 'No (N)'	System	02 Nov 2020 11:21:05

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-11-02T06:20:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5f79f44b-2be1-4c1a-8ce8-b1f97a605c7b'	System	02 Nov 2020 11:21:05
User entered 'No (N)'	System	02 Nov 2020 11:21:05

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-02T06:20:59', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5f79f44b-2be1-4c1a-8ce8-b1f97a605c7b'	System	02 Nov 2020 11:21:05
User entered '02 Nov 2020 06:20:59'	System	02 Nov 2020 11:21:05

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 106'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-11-09T17:55:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6cd99fbd-9168-421f-a09d-2e9084bf88d7'	System	09 Nov 2020 22:55:53
User entered 'No (N)'	System	09 Nov 2020 22:55:53

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-11-09T17:55:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6cd99fbd-9168-421f-a09d-2e9084bf88d7'	System	09 Nov 2020 22:55:53
User entered 'No (N)'	System	09 Nov 2020 22:55:53

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-09T17:55:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6cd99fbd-9168-421f-a09d-2e9084bf88d7'	System	09 Nov 2020 22:55:53
User entered '09 Nov 2020 17:55:48'	System	09 Nov 2020 22:55:53

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '09 Nov 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '13 Nov 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 113'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-11-16T18:28:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ffdd3ef4-c979-4e1e-a289-3a96aaa8b7ff'	System	16 Nov 2020 23:28:48
User entered 'No (N)'	System	16 Nov 2020 23:28:48

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-11-16T18:28:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ffdd3ef4-c979-4e1e-a289-3a96aaa8b7ff'	System	16 Nov 2020 23:28:48
User entered 'No (N)'	System	16 Nov 2020 23:28:48

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-16T18:28:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ffdd3ef4-c979-4e1e-a289-3a96aaa8b7ff'	System	16 Nov 2020 23:28:48
User entered '16 Nov 2020 18:28:44'	System	16 Nov 2020 23:28:48

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '16 Nov 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '20 Nov 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 Sep 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Sep 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Oct 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 Oct 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Oct 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 Oct 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Oct 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 Oct 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-11-22T14:16:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered 'Yes (Y)'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

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 (c44ed63bfc4063fb)', Time: '2020-11-22T14:16:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered 'No (N)'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-11-22T14:16:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered 'No (N)'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[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 (c44ed63bfc4063fb)', Time: '2020-11-22T14:17:04', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered 'Yes (Y)'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Please 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 (c44ed63bfc4063fb)', Time: '2020-11-22T14:17:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-22T14:17:15', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered '22 Nov 2020 14:17:15'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:11:21
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Oct 2020 16:33:39
	(b) (4)	

US3412013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:11:21
User entered '22 Oct 2020'	Mason Urban (b) (4)	22 Oct 2020 16:33:39
	(b) (4)	

US3412013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:11:21
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	22 Oct 2020 16:33:39
	(b) (4)	

US3412013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:11:21
User entered empty.	Mason Urban (b) (4)	22 Oct 2020 16:33:39
	(b) (4)	

US3412013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:11:24
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Oct 2020 16:33:46
	(b) (4)	

US3412013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 16:33:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:50

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:18
User entered '02 Oct 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:37:54
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:50

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:32:10
User closed query 'Per source visit scheduled for 11:00? ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 01:32:07
Query 'Per source visit scheduled for 11:00? ' answered with 'information for time confirmed and updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:41:50
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:41:29
User entered '11:00' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:41:29
User opened query 'Per source visit scheduled for 11:00? ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:39:02
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:18
Query 'Data is required. Please complete.' answered with 'time is unknown' (Site from System).	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:38:03
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:37:54
User entered empty.	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:37:54

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:50

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:00'	System	05 Nov 2020 19:41:29
User entered empty.	System	02 Oct 2020 17:37:54

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:50

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:18
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:54
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:50

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:54
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:49
User entered 'Day 1 (Day 1)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Date](#)

Audit	User	Time (GMT)
User closed query 'Please add 01 Oct 2020 as per source this is when symptoms started' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 01:33:06
Query 'Please add 01 Oct 2020 as per source this is when symptoms started' answered with '01 oct 2020 has been added' (Site from CRA).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:24
User opened query 'Please add 01 Oct 2020 as per source this is when symptoms started' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:40:42
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:30
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered '02 Oct 2020'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:31
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:33
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:37
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered '36.9' C	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:40
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'Severe (Severe)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:41
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:44
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:46
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:49
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Melissa Fuson (b) (4)	04 Nov 2020 15:14:46
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Nov 2020 15:14:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:50
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'Moderate (Moderate)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:53
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'Severe (Severe)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:54
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'Severe (Severe)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'Severe (Severe)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Melissa Fuson (b) (4)	04 Nov 2020 15:19:41
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Nov 2020 15:19:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:58
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'Severe (Severe)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:49:00
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:49:02
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:49:04
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 15:49:05
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:48:01
User entered 'Mild (Mild)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:49
User entered 'Day 2 (Day 2)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Date](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.7' F	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Cough](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Severe (Severe)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:49
User entered 'Day 3 (Day 3)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Date](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.3' F	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Cough](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

Fatigue

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:49
User entered 'Day 4 (Day 4)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Date](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Cough](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

Fatigue

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:49
User entered 'Day 5 (Day 5)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Date](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Cough](#)

Audit	User	Time (GMT)
User entered 'Severe (Severe)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:49
User entered 'Day 6 (Day 6)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Date](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.4' F	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Cough](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 1 (Day 1)'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Date](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

Fatigue

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 2 (Day 2)'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Date](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

Fatigue

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Date](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

Fatigue

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:50

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered '02 Oct 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:40:10
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:50

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:40:10
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:50

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:40:10
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:50

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered '02 Oct 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:40:10
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:50

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Steven Anderson (b) (4)	02 Oct 2020 17:40:10
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:50

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:40:10
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:50

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:40:10
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:50

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:40:10
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:50

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:40:10
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:50

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 17:40:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:23:50

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:41:00
DataPoint Un-verified.	Melissa Fuson (b) (4)	04 Nov 2020 15:33:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 15:33:41
DataPoint Verified.	Melissa Fuson (b) (4)	04 Nov 2020 15:33:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:33:01
User entered 'Yes (Y)'	Steven Anderson (b) (4)	13 Oct 2020 17:42:21
	(b) (4)	

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:23:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:23:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:23:50

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 04:28:23
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'DATES ARE CORRECT PER PPD SPECIMEN RECEIVED STATEMENT. DAY 3 (1F619521068) AND DAY 5(1F621099106) WERE COLLECTED AND RECEIVED THE SAME DAY) PER REQUESTION FORM SAMPLE DATA(DAY3-(03-OCT-2020) & (DAY5-(06-OCT-2020) WERE COLLECTED. RECEIVING SAMPLES COULD BE OFF DUE TO B ACKLOG' (Site from DM).	Melissa Fuson (b) (4)	16 Nov 2020 15:48:28
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 07:02:57
User closed query 'Please confirm collection date' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 22:29:09
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
Query 'Please confirm collection date' answered with 'collection confirmed' (Site from CRA).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 17:41:47
User entered '04 Oct 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 17:41:36
User opened query 'Please confirm collection date' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:49:15
User entered '03 Oct 2020'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:23:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:23:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:23:50

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Please confirm collection date' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 22:29:03
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
Query 'Please confirm collection date' answered with 'collection date confirmed' (Site from CRA).	Mylene Asmar-Rios	05 Nov 2020 17:55:03
User opened query 'Please confirm collection date' (Site from CRA).	(b) (4)	04 Nov 2020 21:49:24
	(b) (4), (b) (6)	
User entered '06 Oct 2020'	Mylene Asmar-Rios	04 Nov 2020 18:06:55
	(b) (4)	

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:23:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:23:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:23:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered empty.	Myelene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:23:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:23:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:23:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:23:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:23:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:23:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:23:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:23:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:23:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:23:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:23:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:23:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:41:39
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:41:39
User entered '02 Oct 2020'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:41:39
User entered 'Clinic (Clinic)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered 'Yes (Y)'	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '02 Oct 2020'	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '11:25'	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:25'	System	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '167.5' cm	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	
DataPoint set to visible.	System	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '87.3' kg	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	
DataPoint set to visible.	System	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '36.9' C	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered 'Oral (Oral)'	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered empty.	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '94'	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '17'	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '120'	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '60'	Mylene Asmar-Rios	04 Nov 2020 18:05:48
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:25
User entered 'Yes (Y)'	Mylene Asmar-Rios	04 Nov 2020 18:05:59
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:25
User entered '02 Oct 2020'	Mylene Asmar-Rios	04 Nov 2020 18:05:59
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:23:50

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:40
User entered 'Yes (Y)'	Mylene Asmar-Rios	04 Nov 2020 18:06:10
	(b) (4)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:23:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:42:40
User entered '02 Oct 2020'	Mylene Asmar-Rios	04 Nov 2020 18:06:10
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:41:16
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:36:22
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please confirm if the subject was evaluated for COVID-19' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:15:37
Query 'Per MM, please confirm if the subject was evaluated for COVID-19' answered with 'yes the subject was evaluated for COVID-19 and results came back negative ' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:09:00
User opened query 'Per MM, please confirm if the subject was evaluated for COVID-19' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 08:16:08
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 17:38:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:38:51
Data point term sent to Coder	System	02 Oct 2020 17:37:38
User entered 'upper respiratory infection'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '29 Sep 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'None (NONE)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '1'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:02:58
User entered 'USA-US061-2020-mRNA-1273-P301000014'	System	24 Nov 2020 13:02:50
User entered 'New'	(b) (4), (b) (6)	24 Nov 2020 13:02:50

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Animal bite, LLT: Cat bite - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:58:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:58:00
Data point term sent to Coder	System	23 Nov 2020 21:30:30
User entered 'Catbite'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
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 'Subject has not been discharged yet. Therefor discharge date will still be missing' (Site from System).	Steven Anderson (b) (4)	23 Nov 2020 21:32:11
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	23 Nov 2020 21:29:39
User entered '1'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Nov 2020'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	23 Nov 2020 21:31:36
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		23 Nov 2020 21:31:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	23 Nov 2020 21:31:36
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	23 Nov 2020 21:29:39
User entered 'Unknown (UNK)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	23 Nov 2020 21:32:16
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).	System	23 Nov 2020 21:32:16
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	23 Nov 2020 21:32:16
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4)	23 Nov 2020 21:31:36
User entered empty.	System	23 Nov 2020 21:31:36
	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[None](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject noticed us through e-diary that she had contact with a medical provider. She went to see her PCP on 20-Nov-2020 to follow up on her persistent cough. he advised her on some OTC medications to try. She has yet to try any he recommended. On friday entry she was bit by her cat on her left hand. on saturday 21Nov2020 she went to Good Sam ER with redness, swelling, and pain in her left hand. She was told to watch and wait and return if worsened. She returned to Good Sam ER on Sunday 22 Nov 2020 and admitted for a severe infection in her left hand due to catbite. She has been started on Vancomycin IV and is waiting for consult from a hand surgeon this afternoon. Her cough has also worsened today and she is discussing it with her hospitalist today. Site will call her tomorrow to check in and obtain more information.'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 21:31:36
User entered '0'	System	23 Nov 2020 21:29:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:50

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:57:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:59:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:59:22
Data point term sent to Coder	System	19 Aug 2020 16:58:59
User entered 'LISINOPRIL'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'HTN'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 16:58:54
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:03:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:03:28
Data point term sent to Coder	System	19 Aug 2020 17:02:09
User entered 'ATROVASTATIN'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'HLD'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '40'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:01:21
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:59:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:59:23
Data point term sent to Coder	System	19 Aug 2020 17:04:14
User entered 'GLIMEPIRIDE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'T2DM'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '2'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:04:01
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:07:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:07:20
Data point term sent to Coder	System	19 Aug 2020 17:06:17
User entered 'ESTRADIOL'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:07:06
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'date of last menopause was listed in medical history . ' (Site from DM).	Jacob sekinger (b) (4)	29 Sep 2020 16:09:28
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:23:48
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'POST-MENOPAUSE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '.5'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:05:32
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
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: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:09:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:09:25
Data point term sent to Coder	System	19 Aug 2020 17:08:22
User entered 'OMEPRAZOLE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'GERD'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '40'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:07:29
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:11:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:11:22
Data point term sent to Coder	System	19 Aug 2020 17:10:31
User entered 'CLONAZEPAM'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'ANXIETY'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '.5'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:09:36
User entered 'UN UNK 2014'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: ANTIVERTIGO PREPARATIONS, ATC: ANTIVERTIGO PREPARATIONS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:09:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:09:25
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Data point term sent to Coder	System	19 Aug 2020 17:13:39
User entered 'MCLIZINE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'VERTIGO'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '25'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:13:23
User entered 'UN UNK 2015'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: FAMCICLOVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:40:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:40:28
Data point term sent to Coder	System	19 Aug 2020 17:15:44
User entered 'FAMCICLOVIR'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'FEVER BLISTERS'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '250'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:15:26
User entered 'UN UNK 2018'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: MIDODRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 12:53:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 12:53:49
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Data point term sent to Coder	System	19 Aug 2020 17:18:51
User entered 'MIDODRINE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'DYSAUTONOMIA'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '5'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:18:48
User entered 'UN UNK 2015'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 17:47:14
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 17:47:14
Data point term sent to Coder	System	19 Aug 2020 17:24:00
User entered 'JANUVIA'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'T2DM'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '100'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:23:38
User entered 'UN UNK 2019'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
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)	14 Sep 2020 23:39:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 23:39:49
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 23:27:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 23:27:06
Data point term sent to Coder	System	19 Aug 2020 17:26:03
User entered 'VITAMIN D'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'GENERAL SUPPLEMENT'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '25'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:07:31
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' answered with 'this is what is used by patient ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 20:55:59
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:24:07
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:25:36
User entered 'UN UNK 2019'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: PREGABALIN, PRODUCTSYNONYM: LYRICA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 11:37:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 11:37:47
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Data point term sent to Coder	System	19 Aug 2020 17:30:21
User entered 'LYRICA'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'DYSAUTONOMIA'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '300'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'twice daily (BID)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Myelene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2015). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 19:12:17
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2015). Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'OK' (Site from DM).	Mylene Asmar-Rios (b) (4)	29 Sep 2020 21:23:35
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2015). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:24:26
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:30:06
User entered 'UN UNK 2008'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: CANAGLIFLOZIN, PRODUCTSYNONYM: INVOKANA [CANAGLIFLOZIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 05:09:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	16 Sep 2020 05:09:49
Data point term sent to Coder	System	10 Sep 2020 16:08:44
User entered 'INVOCANA'	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'DMT2'	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '100'	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'mg (mg)'	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'once daily (QD)'	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'UN UNK 2020'	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '0'	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Yes (Y)'	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 16:08:39
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
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)	12 Oct 2020 13:21:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 13:21:15
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 13:20:22
Coding entries removed.	Mylene Asmar-Rios	12 Oct 2020 13:19:23
	(b) (4)	
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)	02 Oct 2020 12:35:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 12:35:48
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 12:34:48
Coding entries removed.	Steven Anderson (b) (4)	02 Oct 2020 12:34:25
	(b) (4)	
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)	10 Sep 2020 16:10:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 16:10:39
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 16:09:48
User entered 'TYLENOL'	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User closed query 'Per CDM re-query: Please confirm if the 'INJECTION SITE PAIN' meets the criteria for an Adverse Event and if so, ensure it is captured on the AE page as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 06:46:00
Query 'Per CDM re-query: Please confirm if the 'INJECTION SITE PAIN' meets the criteria for an Adverse Event and if so, ensure it is captured on the AE page as appropriate.' answered with 'UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	12 Oct 2020 13:19:31
User entered 'INJECTION SITE PAIN "SOLICITED EVENT"' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	12 Oct 2020 13:19:23
User opened query 'Per CDM re-query: Please confirm if the 'INJECTION SITE PAIN' meets the criteria for an Adverse Event and if so, ensure it is captured on the AE page as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:33:48
User closed query 'Per DM CLR: Please note that there is no AE or record in eDiary that matches this Con Med indication during this time frame. If the 'INJECTION SITE PAIN "AE"' is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of 'INJECTION SITE PAIN "AE"' did not meet the AE reporting and update the field of 'Was this medication taken for solicited event?' as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:33:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE or record in eDiary that matches this Con Med indication during this time frame. If the 'INJECTION SITE PAIN "AE"' is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of 'INJECTION SITE PAIN "AE"' did not meet the AE reporting and update the field of 'Was this medication taken for solicited event?' as appropriate. ' answered with 'term has been updated to solicited ae' (Site from DM).	Steven Anderson (b) (4)	02 Oct 2020 12:34:41
User entered 'INJECTION SITE PAIN "Solicited AE"' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Oct 2020 12:34:25
User opened query 'Per DM CLR: Please note that there is no AE or record in eDiary that matches this Con Med indication during this time frame. If the 'INJECTION SITE PAIN "AE"' is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of 'INJECTION SITE PAIN "AE"' did not meet the AE reporting and update the field of 'Was this medication taken for solicited event?' as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 05:09:39
User entered 'INJECTION SITE PAIN "AE"'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '500'	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'mg (mg)'	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'as needed (PRN)'	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'UN UNK 2020'	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '0'	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Yes (Y)'	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 16:09:32
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Oct 2020 12:34:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX COUGH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:49:07
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 Nov 2020 04:49:07
Data point term sent to Coder	System	03 Nov 2020 19:50:46
Coding entries removed.	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 19:50:19
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	03 Nov 2020 17:38:30
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX COUGH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 05:24:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 05:24:43
Data point term sent to Coder	System	02 Oct 2020 17:44:52
User entered 'mucinex cough syrup'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:50:19
User closed query 'Please type out' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:50:16
Query 'Please type out' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	03 Nov 2020 19:50:28
User entered 'Upper respiratory Infection AE' reason for change: Data Entry Error	Jacob sekinger (b) (4)	03 Nov 2020 19:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:32
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User opened query 'Please type out' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:36:52
User entered 'URI AE'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'unk'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Please confirm dose' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 01:30:58
Query 'Please confirm dose' answered with 'PATIENT DID NOT KNOW DOSAGE' (Site from CRA).	Melissa Fuson (b) (4)	04 Nov 2020 15:52:23
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User opened query 'Please confirm dose' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:37:33
User entered 'Other (OTHER)'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'none'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'other (OTHER)'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'q6hr / prn'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '29 Sep 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Please confirm and update if appropriate' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 01:31:43
Query 'Please confirm and update if appropriate' answered with 'confirmed' (Site from CRA).	Jacob sekinger (b) (4)	03 Nov 2020 19:50:55
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:38:35
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User opened query 'Please confirm and update if appropriate' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:38:19
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:45:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 17:45:57
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Oct 2020 17:45:57
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:44:40
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:44:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:15:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:15:34
Data point term sent to Coder	System	03 Nov 2020 19:51:49
Coding entries removed.	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 19:51:33
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: OTHER THROAT PREPARATIONS, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:15:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:15:52
Data point term sent to Coder	System	02 Oct 2020 17:45:54
User entered 'advil'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Please type out' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:50:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:50:29
Query 'Please type out' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	03 Nov 2020 19:51:50
User entered 'Upper respiratory infection AE' reason for change: Data Entry Error	Jacob sekinger (b) (4)	03 Nov 2020 19:51:33
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:52
User opened query 'Please type out' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:38:49
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'URI AE'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '200'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'mg (mg)'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'as needed (PRN)'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '29 Sep 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Please confirm and update if appropriate' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 01:31:12
Query 'Please confirm and update if appropriate' answered with 'confirmed' (Site from CRA).	Jacob sekinger (b) (4)	03 Nov 2020 19:51:57
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:39:29
User opened query 'Please confirm and update if appropriate' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:39:27
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:45:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 17:45:34
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Oct 2020 17:45:34
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:45:28
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:45:28
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:23:50

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:41:25
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 16:10:23
	(b) (4)	

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

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

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 08:03'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:50

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.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 13:03:18