

US3832014 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:21:29

All time stamps listed in this document are displayed in GMT

US3832014

Form: Participant Creation

Generated On: 26 Nov 2020 11:21:29

[Participant ID](#)

US3832014

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

US3832014

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	31 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	56
Age Units	YEARS
Age (Derived)	56
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

US3832014

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:29

Date of Informed Consent (<i>dd MMM yyyy</i>)	31 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

US3832014

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:21:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3832014

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:21:29

Were any significant conditions reported?

Yes ☒

No ☐

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:29

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:29

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)	

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:29

Condition	CHRONIC COUGH
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)	_____

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:29

Condition	PLEURISY
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)	

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:29

Condition	BENIGN TUMOR RIGHT ARM
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:29

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:29

Condition	BENIGN LEFT BREAST MASS
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:29

Condition	BROKEN LEFT ANKLE
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:29

Condition	MUSCLE SPASMS
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	31 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	14:18 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 14:18
Height (<i>xxx.x</i>)	66 in
Weight (<i>xxx.x</i>)	182 lb
BMI (<i>xxx.x</i>)	29.43699 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)	

US3832014

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 2020

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

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:29

Date of assessment (*dd MMM yyyy*) 31 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 (*dd MMM yyyy*) UN UNK 2000

Date of surgery unknown False

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

Date of last menstruation unknown False

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3832014

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	31 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:29

What was the date of randomization? (dd MMM yyyy) 31 JUL 2020

What was the participant's randomization number? 142473

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 ☒

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:29

Height	ND - Not Done
Weight	ND - Not Done

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

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)	31 JUL 2020
Time of assessment (00:00-23:59)	14:18 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 14:18
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

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)	31 JUL 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 15:00
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3832014

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

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.

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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) 31 JUL 2020

What was the treatment time? (00:00-23:59) 14:30 (24 HR)

Treatment Date and Time (derived) 31 JUL 2020 14:30

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

US3832014

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

31 JUL 2020

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

14:24 (24 HR)

Collection date and time (derived)

31 JUL 2020 14:24

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:29

Collection date (<i>dd MMM yyyy</i>)			31 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	14:23	31 JUL 2020 14:23
Nasopharyngeal Swab 2	No		

US3832014

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 31 JUL 2020 14:50

PC Close Date & Time 31 JUL 2020 17:20

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

31 JUL 2020 18:15

PC Close Date & Time

01 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

02 AUG 2020 10:39

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

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

98.3 °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

02 AUG 2020 12:00

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 03 AUG 2020 12:00

PC Close Date & Time 04 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 04 AUG 2020 12:00

PC Close Date & Time 05 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 05 AUG 2020 12:00

PC Close Date & Time 06 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 06 AUG 2020 12:00

PC Close Date & Time 07 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

31 JUL 2020 14:50

PC Close Date & Time

31 JUL 2020 17:20

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

31 JUL 2020 18:15

PC Close Date & Time

01 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 10:42

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

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

02 AUG 2020 12:01

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

31 JUL 2020 14:50

PC Close Date & Time

31 JUL 2020 17:20

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

31 JUL 2020 18:15

PC Close Date & Time

01 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

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 ☒

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

Yes ☐	
PC Time stamp	02 AUG 2020 10:41
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

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 ☒

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

Yes ☐	
PC Time stamp	02 AUG 2020 12:01
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

Was Contact Attempted?

Yes ☒

No ☐

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

07 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832014

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832014

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

Was Contact Attempted?

Yes ☒

No ☐

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

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832014

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:48
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:43
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3832014

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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)	28 AUG 2020
What was the treatment time? (00:00-23:59)	12:13 (24 HR)
Treatment Date and Time (derived)	28 AUG 2020 12:13
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

US3832014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

28 AUG 2020

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

12:06 (24 HR)

Collection date and time (derived)

28 AUG 2020 12:06

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:29

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:03	28 AUG 2020 12:03
Nasopharyngeal Swab 2	No		

US3832014

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 14:49

PC Open Date & Time

28 AUG 2020 12:33

PC Close Date & Time

28 AUG 2020 15:03

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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 98.4 °F

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

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

PC Time Stamp	28 AUG 2020 16:21
PC Open Date & Time	28 AUG 2020 15:58
PC Close Date & Time	29 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

29 AUG 2020 21:20

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

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

98.6 °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 12:00

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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 12:17

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

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

97.2 °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 12:08

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 10:57

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

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

98.6 °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

03 SEP 2020 12:01

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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

28 AUG 2020 14:49

PC Open Date & Time

28 AUG 2020 12:33

PC Close Date & Time

28 AUG 2020 15:03

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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

28 AUG 2020 16:22

PC Open Date & Time

28 AUG 2020 15:58

PC Close Date & Time

29 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

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

29 AUG 2020 21:21

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

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

30 AUG 2020 12:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

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

31 AUG 2020 12:17

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

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

01 SEP 2020 12:08

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

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 SEP 2020 10:57

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

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

03 SEP 2020 12:02

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 14:50
PC Open Date & Time	28 AUG 2020 12:33
PC Close Date & Time	28 AUG 2020 15:03

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 16:23
PC Open Date & Time	28 AUG 2020 15:58
PC Close Date & Time	29 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

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 ☒

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

Yes ☐	
PC Time stamp	29 AUG 2020 21:22
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

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 ☒

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

Yes ☐	
PC Time stamp	30 AUG 2020 12:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

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 ☒

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

Yes ☐	
PC Time stamp	31 AUG 2020 12:18
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

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 ☒

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

Yes ☐	
PC Time stamp	01 SEP 2020 12:09
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

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 ☒

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

Yes ☐	
PC Time stamp	03 SEP 2020 10:58
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

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 ☒

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832014

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832014

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832014

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	1 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:38 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:38
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	100 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3832014

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3832014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	1 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:53 (24 HR)
Collection date and time (derived)	1 OCT 2020 10:53

US3832014

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 OCT 2020 08:52:52

Patient Cloud Open Date & Time

30 SEP 2020 00:01

Patient Cloud Close Date & Time

04 OCT 2020 23:59

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

09 OCT 2020 14:40:58

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 09:40:37

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

28 OCT 2020 01:18:50

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

06 NOV 2020 09:53:50

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

11 NOV 2020 01:17:36

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

01 OCT 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

08 OCT 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

15 OCT 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

22 OCT 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 23:59:50

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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°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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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02 SEP 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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27 JAN 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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03 FEB 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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

Date and time of submission

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06 FEB 2022 00:01

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10 FEB 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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

Date and time of submission

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13 FEB 2022 00:01

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17 FEB 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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

Date and time of submission

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20 FEB 2022 00:01

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24 FEB 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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

Date and time of submission

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27 FEB 2022 00:01

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03 MAR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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

Date and time of submission

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06 MAR 2022 00:01

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10 MAR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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17 MAR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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31 MAR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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07 APR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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21 APR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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12 MAY 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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°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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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19 MAY 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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26 MAY 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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02 JUN 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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09 JUN 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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16 JUN 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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23 JUN 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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30 JUN 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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07 JUL 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

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

Date and time of submission

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10 JUL 2022 00:01

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14 JUL 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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°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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3832014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

Was Contact Attempted?

Yes ☒

No ☐

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

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832014

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832014

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3832014

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:21:29

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3832014

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:21:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

AEID	USA-US100-2020-MRNA-1273-P30 1000003
Adverse event	HYPERTENSIVE EMERGENCY
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)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	02 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	31 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	02 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	348 of 2135

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

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	

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

BASED ON REVIEW OF
MEDICAL RECORDS RECEIVED
ON 01 OCT 2020 THE
FOLLOWING INFORMATION
HAS BEEN UPDATED
ADMISSION DATE 31 AUG 2020
DISCHARGE DATE 02 SEP 2020
ADMIN DIAGNOSIS
HYPERTENSIVE EMERGENCY
(LIKELY CAUSED BY ACUTE
BACK PAIN WHICH RESULTED
IN HYPERTENSION,
TACHYCARDIA AND ANXIETY).
08/31/2020 SUBJECT WAS SEEN
IN THE ER EARLY IN THE DAY
FOR ABDOMINAL PAIN. THE
SUBJECT WAS TREATED WITH
MORPHINE FOR PAIN AND HAD
A CT SCAN OF ABDOMEN AND
PELVIS WHICH WERE BOTH
FOUND TO BE WITHIN NORMAL
LIMITS WITH NO SPECIFIC
CAUSE FOR PAIN. THE SUBJECT
LATER RETURNED THAT DAY
WITH SEVERE HEADACHE AND
LEFT UPPER QUADRANT
ABDOMINAL PAIN. THE
SUBJECT WAS FOUND ON THE
BATHROOM FLOOR. IT IS
UNCLEAR HOW SHE ENDED UP
ON THE BATHROOM FLOOR.
VITALS OBTAINED 08/31/2020
AT 1402 BY ER TRIAGE WITH
THE FOLLOWING FINDINGS: HR
113 B/P 242/136. SUBJECT WAS
ADMITTED AT THIS TIME

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

POINT WITH NONDESCRIPT
ABDOMINAL PAIN, WITH
NOTED NEGATIVE X-RAY AND
CT. CONCERN WAS NOTED
THAT THIS EPISODE MAY BE
REPRESENTATIVE OF
WITHDRAWAL SINCE THE
SUBJECT HAS NOT BEEN ON
HER PAIN MEDICATION FOR
THE BETTER PART OF THE
DAY. THE SUBJECT REMAINS
CONFUSED AND GIVEN THE
HYPERTENSIVE EMERGENCY,
STROKE HAS BEEN NOTED AS
A DIFFERENTIAL, BUT
FORTUNATELY SHE HAS NO
ACUTE UNILATERAL DEFICITS.
SUBJECT WAS ADMITTED TO
ICU WITH THE FOLLOWING
PLAN:
HYPERTENSIVE EMERGENCY:
STARTED ON A CARDENE DRIP
AND AN ECHO. ECHO WNL
ALTERED MENTAL STATUS:
STAT CT OF HEAD WNL
HYPERGLYCEMIA: MONITOR
WITH COLLECTION OF A
HGA1C
ELEVATED BRAIN
NATRIURETIC PEPTIDE LEVEL:
CONTINUE TO MONITOR
ABDOMINAL PAIN: CT
COMPLETED WNL WITH NO
ACUTE PATHOLOGY.
ALL COLLECTED
INFORMATION AND
CONMENDS HAVE BEEN

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

UPDATED.	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

AEID	
Adverse event	ALTERED MENTAL STATUS
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)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	02 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	353 of 2135

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

AEID	
Adverse event	HYPERGLYCEMIA
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)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	2 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	355 of 2135

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

AEID	
Adverse event	ELEVATED BRAIN NATRIURETIC PEPTIDE LEVEL
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)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	02 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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)	
357 of 2135	

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

AEID	
Adverse event	ABDOMINAL PAIN
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)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	02 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	359 of 2135

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

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	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:21:29

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

Yes ☒

No ☐

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	SPIRIVA HANDIHALER
Prophylaxis	Yes ☐ No ☒
Indication	COPD- CHRONIC OBSTRUCTIVE PULMONARY DISEASE
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

	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 2013	
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	☒

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	COMBIVENT
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Dose per administration	100/20
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

	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 2013	
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	☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	CLONIDINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	0.3
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

	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	☒

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	XOPENEX
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Dose per administration	1.25
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

	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 2013	
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	☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	FLOVENT
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Dose per administration	88
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

	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 2013
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	☒

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

Name of Medication HYDROMET 5 MG-1.5 MG/5 ML
ORAL SYRUP
[HYDROCODONE/HOMATROPIN
E]

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	PERCOCET
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Dose per administration	7.5/325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	TIZANIDINE
Prophylaxis	Yes ☐ No ☒
Indication	MUSCLE SPASMS IN THE LOWER BACK
Dose per administration	4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☒ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

	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 2013
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)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSIVE EMERGENCY
Dose per administration	650
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	MAALOX PLUS
Prophylaxis	Yes ☒ No ☐
Indication	REFLUX PROPHYLAXIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	DOSE
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	ADMELOG
Prophylaxis	Yes ☐ No ☒
Indication	HYPERGLYCEMIA
Dose per administration	1-10
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	ATIVAN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSIVE EMERGENCY
Dose per administration	0.5
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	MELATONIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSIVE EMERGENCY
Dose per administration	3
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	MORPHINE SULFATE
Prophylaxis	Yes ☐ No ☒
Indication	ABDOMINAL PAIN
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	CARDENE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSIVE EMERGENCY
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	ZOFRAN
Prophylaxis	Yes ☒ No ☐
Indication	NAUSEA PROPHYLAXIS
Dose per administration	4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	PERCOCET
Prophylaxis	Yes ☐ No ☒
Indication	ABDOMINAL PAIN
Dose per administration	7.5/325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	PROTONIX
Prophylaxis	Yes ☒ No ☐
Indication	ACID REFLUX PROPHYLAXIS
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

Name of Medication	GLYCOLOX
Prophylaxis	Yes ☒ No ☐
Indication	CONSTIPATION PROPHYLAXIS
Dose per administration	17
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 ☐

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:21:29

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:21:29

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 AUG 2020	ECHOCARDIOGRAM	Adverse Event	
31 AUG 2020	CT SCAN OF PELVIS AND ABDOMEN	Adverse Event	
31 AUG 2020	CT SCAN OF HEAD	Adverse Event	

US3832014

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:21:29

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

US3832014

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:21:29

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 ☐

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:21:29

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/SEP/2020 13:49
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

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:21:29

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/OCT/2020 08:16
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

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:21:29

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/OCT/2020 12:54
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

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:21:29

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/NOV/2020 14:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:21:29

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/NOV/2020 17:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3832014 (Prod: Keystone VitaLink Research - Anderson - PPDS)

US3832014

Form: Participant Creation

Generated On: 26 Nov 2020 11:21:29

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3832014'	RWS_ENDPOINT ENDPOINT (b) (4) 	31 Jul 2020 17:34:16

US3832014

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:04
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:29

US3832014

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:04
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 17:34:17

US3832014

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:04
User entered 'Clinic (Clinic)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:29

US3832014

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	01 Aug 2020 21:58:29

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 17:34:18

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '56'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '56'	System	01 Aug 2020 21:59:06

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered 'Female (F)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

White

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '1'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:29

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:29

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered '31 Jul 2020'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:59:06

US3832014

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	01 Aug 2020 21:59:06

US3832014

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '2020'	System	01 Aug 2020 21:59:06

US3832014

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:29

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered 'Amendment 1 (1)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:59:06

US3832014

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:59:06

US3832014

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:59:06

US3832014

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:59:06

US3832014

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:59:06

US3832014

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 17:34:17

US3832014

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 21:59:11

US3832014

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:50:32
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:59:11

US3832014

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:21:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:50:56
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 21:59:23

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User closed query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 09:09:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 11:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 11:52:39
Data point term sent to Coder	System	21 Sep 2020 11:51:43
Query 'Per MM, please expand the abbreviation.' answered with 'Chronic obstructive pulmonary disease' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	21 Sep 2020 11:51:09
Coding entries removed.	Alyssa-Kay Peay (b) (4) (b) (4)	21 Sep 2020 11:51:03
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	21 Sep 2020 11:51:03
User opened query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:54:16
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:05:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:05:13
Data point term sent to Coder	System	01 Aug 2020 22:04:40
User entered 'COPD'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:47

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1999'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:47

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:47

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:47

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:47

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:47

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	01 Aug 2020 22:03:47

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '1999'	System	01 Aug 2020 22:03:47

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 22:03:47

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 22:03:47

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
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)	01 Aug 2020 22:05:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:05:13
Data point term sent to Coder	System	01 Aug 2020 22:04:39
User entered 'HYPERTENSION'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:12

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2010'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:12

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:12

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:12

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:12

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:12

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	01 Aug 2020 22:04:12

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '2010'	System	01 Aug 2020 22:04:12

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 22:04:12

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 22:04:12

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Chronic cough - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:05:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:05:13
Data point term sent to Coder	System	01 Aug 2020 22:04:40
User entered 'CHRONIC COUGH'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:29

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2010'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:29

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:29

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:29

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:29

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:29

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	01 Aug 2020 22:04:29

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '2010'	System	01 Aug 2020 22:04:29

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 22:04:29

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 22:04:29

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pleural infections and inflammations, PT: Pleurisy, LLT: Pleurisy - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 17:25:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 17:25:10
User closed query 'For coding purposes, please split to report each event separately to capture coding for all terms. Example: 1) CHEST PAIN (Specify if cardiac or non-cardiac) 2) LUNG PAIN' (Site from System).	System	24 Aug 2020 17:24:50
Query 'For coding purposes, please split to report each event separately to capture coding for all terms. Example: 1) CHEST PAIN (Specify if cardiac or non-cardiac) 2) LUNG PAIN' answered with 'data corrected' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 17:24:50
User entered 'Pleurisy' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 17:24:38
User opened query 'For coding purposes, please split to report each event separately to capture coding for all terms. Example: 1) CHEST PAIN (Specify if cardiac or non-cardiac) 2) LUNG PAIN' (Site from System).	Coder Import (b) (4)	03 Aug 2020 15:41:58
Data point term sent to Coder	System	01 Aug 2020 22:05:41
User entered 'CHEST/LUNG PAIN'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:59
	(b) (4)	

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2010'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:59

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:59

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:59

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:59

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:59

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	01 Aug 2020 22:04:59

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '2010'	System	01 Aug 2020 22:04:59

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 22:04:59

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 22:04:59

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Cutaneous neoplasms benign, HLT: Skin neoplasms benign, PT: Benign neoplasm of skin, LLT: Benign neoplasm of skin - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:27:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:27:10
Data point term sent to Coder	System	01 Aug 2020 22:05:41
User entered 'BENIGN TUMOR RIGHT ARM'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:05:35

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1981'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:05:35

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:05:35

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:05:35

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1981'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:05:35

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:05:35

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	01 Aug 2020 22:05:35

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '1981'	System	01 Aug 2020 22:05:35

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	01 Aug 2020 22:05:35

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '1981'	System	01 Aug 2020 22:05:35

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:07:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:07:13
Data point term sent to Coder	System	01 Aug 2020 22:06:41
User entered 'APPENDICITIS'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:08

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1992'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:08

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:08

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:08

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1992'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:08

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:08

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	01 Aug 2020 22:06:08

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '1992'	System	01 Aug 2020 22:06:08

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	01 Aug 2020 22:06:08

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '1992'	System	01 Aug 2020 22:06:08

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms benign (incl nipple), HLT: Breast and nipple neoplasms benign, PT: Benign breast neoplasm, LLT: Breast lump (benign) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 13:47:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 13:47:16
Data point term sent to Coder	System	01 Aug 2020 22:07:42
User entered 'BENIGN LEFT BREAST MASS'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:50

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1981'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:50

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:50

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:50

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1981'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:50

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:50

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	01 Aug 2020 22:06:50

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '1981'	System	01 Aug 2020 22:06:50

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	01 Aug 2020 22:06:50

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '1981'	System	01 Aug 2020 22:06:50

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Broken ankle - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 07:31:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 07:31:00
Data point term sent to Coder	System	01 Aug 2020 22:07:42
User entered 'BROKEN LEFT ANKLE'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:16

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2001'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:16

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:16

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:16

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2001'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:16

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:16

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	01 Aug 2020 22:07:16

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '2001'	System	01 Aug 2020 22:07:16

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	01 Aug 2020 22:07:16

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '2001'	System	01 Aug 2020 22:07:16

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:08:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:08:14
Data point term sent to Coder	System	01 Aug 2020 22:07:44
User entered 'MUSCLE SPASMS'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:38

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2013'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:38

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:38

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:38

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:38

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:38

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	01 Aug 2020 22:07:38

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '2013'	System	01 Aug 2020 22:07:38

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 22:07:38

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 22:07:38

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:26:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:26:27
Data point term sent to Coder	System	19 Oct 2020 19:25:34
User entered 'Menorrhagia'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:24:37

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'un UNK 2000'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:24:37

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:24:37

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:24:37

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'un UNK 2000'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:24:37

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:24:37

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	19 Oct 2020 19:24:37

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '2000'	System	19 Oct 2020 19:24:37

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	19 Oct 2020 19:24:37

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '2000'	System	19 Oct 2020 19:24:37

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:20:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:20:29
Data point term sent to Coder	System	19 Oct 2020 19:27:41
User entered 'COMPLETE HYSTERETOMY' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:27:04
Data point term sent to Coder	System	19 Oct 2020 19:26:37
User entered 'Complete Hysterotomy'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:25:55

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'un UNK 2000'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:25:55

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:25:55

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:25:55

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'un UNK 2000'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:25:55

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:25:55

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	19 Oct 2020 19:25:55

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '2000'	System	19 Oct 2020 19:25:55

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	19 Oct 2020 19:25:55

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '2000'	System	19 Oct 2020 19:25:55

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '31 Jul 2020'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '14:18'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 14:18'	System	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '66' in	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02
DataPoint set to visible.	(b) (4) System	01 Aug 2020 21:59:11

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '182' lb	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02
DataPoint set to visible.	(b) (4) System	01 Aug 2020 21:59:11

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '29.43699'	System	16 Sep 2020 23:39:49
User entered '29.4'	System	01 Aug 2020 22:01:02
DataPoint set to visible.	System	01 Aug 2020 21:59:11

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	01 Aug 2020 22:01:02
DataPoint set to visible.	System	01 Aug 2020 21:59:11

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:18:08
Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4)	03 Nov 2020 16:33:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:33:18
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:15
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:13
User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:13:24
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '98.6' F	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'please delete' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:18:12
Query 'please delete' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4)	03 Nov 2020 16:33:30
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:33:18
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:27
User opened query 'please delete' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:14:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered 'Oral (Oral)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:18:15
Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4)	03 Nov 2020 16:33:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:33:18
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:59
User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:14:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '84'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:18:18
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4)	03 Nov 2020 16:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:33:18
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:15:26
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:15:12
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '15'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:18:21
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4)	03 Nov 2020 16:33:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:33:18
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:15:42
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:15:31
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '128'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:18:24
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4)	03 Nov 2020 16:33:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:33:18
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:16:01
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:15:59
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '83'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:42
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:17

US3832014

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:42
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:03:54
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		28 Aug 2020 16:21:18
User entered '31 Jul 2020'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:17

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User entered '31 Jul 2020'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:36

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	01 Aug 2020 22:02:18
User entered 'No (N)' reason for change: Data Entry Error	Ashten Sheriff (b) (4)	01 Aug 2020 22:02:18
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	01 Aug 2020 22:01:36
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:36

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:29

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:59:55
	(b) (4), (b) (6)	27 Oct 2020 15:58:03
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'Data has been updated ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:28:16
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 04:49:51
User entered 'Surgically sterile (SURGICALLY STERILE)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:36

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:29

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:36

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	31 Aug 2020 21:31:20
User entered 'UN UNK 2000' reason for change: Per Alyssa-Kay Peay Query Resolution	(b) (4)	31 Aug 2020 21:31:20
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	01 Aug 2020 22:02:18
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:36

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:29

Date of surgery unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:36

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:36

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:29

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:36

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

[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)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

No Risk Identified

Audit	User	Time (GMT)
User closed query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:42:34
Query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:04:28
User opened query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:01:16
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	02 Aug 2020 16:46:05
User entered '0' reason for change: Data Entry Error	Ashten Sheriff (b) (4)	02 Aug 2020 16:46:05
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4)	02 Aug 2020 16:45:56
User entered '1'	System	02 Aug 2020 16:45:56
	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05
	(b) (4)	

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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)	27 Oct 2020 15:58:39
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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)	27 Oct 2020 15:58:39
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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)	27 Oct 2020 15:58:39
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered '1' reason for change: Data Entry Error	Ashten Sheriff (b) (4)	02 Aug 2020 16:45:56
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

Other

Audit	User	Time (GMT)
User closed query 'please delete' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:59:58
Query 'please delete' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4)	03 Nov 2020 16:32:19
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	03 Nov 2020 16:32:13
	(b) (4)	
User opened query 'please delete' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:23:00
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Ashten Sheriff (b) (4)	02 Aug 2020 16:45:56
	(b) (4)	
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05
	(b) (4)	

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:29

[Specify](#)

Audit	User	Time (GMT)
User closed query 'This section is for living conditions. please delete. ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:00:04
Query 'This section is for living conditions. please delete. ' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4)	03 Nov 2020 16:32:24
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:32:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:42:46
User opened query 'This section is for living conditions. please delete. ' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:42:45
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'participant plans on routinely (e.g., weekly) going to places where people gather (e.g., places of worship, restaurants, bars, sporting events) over the coming months' reason for change: Data Entry Error	Ashten Sheriff (b) (4)	02 Aug 2020 16:45:56
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:38
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:08:17

US3832014

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:38
User entered '31 Jul 2020'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:08:17

US3832014

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:38
User entered 'Clinic (Clinic)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:08:17

US3832014

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	01 Aug 2020 22:08:17

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 18:14:12

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:46
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:31:24
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:31:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 18:14:12
User entered '142473' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 18:14:12

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 18:14:12

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:29

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)	27 Oct 2020 15:59:46
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:08:47

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:29

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)	27 Oct 2020 15:59:46
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:08:47

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:08:47

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:08:47

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:29

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:08:47

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:29

Height

Audit	User	Time (GMT)
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:34:53
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:03
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:04
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:14
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:17
User entered '66' in	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:29

Weight

Audit	User	Time (GMT)
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:34:56
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:09
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:07
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:16
User entered '182' lb	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:29

Height

Audit	User	Time (GMT)
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:34:53
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:03
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:04
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:14
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:17
User entered '66' in	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:29

Weight

Audit	User	Time (GMT)
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:34:56
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:09
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:07
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:16
User entered '182' lb	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '31 Jul 2020'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '14:18'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 14:18'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '98.6' F	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered 'Oral (Oral)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '84'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '15'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '128'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '83'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:29

Height

Audit	User	Time (GMT)
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:34:53
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:03
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:04
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:14
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:17
User entered '66' in	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:29

Weight

Audit	User	Time (GMT)
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:34:56
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:09
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:07
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:16
User entered '182' lb	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '31 Jul 2020'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
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)	10 Aug 2020 17:05:28
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 30 minutes post dose' (Site from System).	Ashten Sheriff (b) (4)	02 Aug 2020 16:44:01
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).		01 Aug 2020 22:12:48
User entered '15:00'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 15:00'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '98.3' F	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered 'Oral (Oral)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '73'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '14'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '128'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '78'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

Was the physical examination performed?

Audit	User	Time (GMT)
User closed query 'Per EDC guidelines, NO should be selected if Day 0 and Day 1 are performed the same day. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:43:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 21:03:45
Query 'Per EDC guidelines, NO should be selected if Day 0 and Day 1 are performed the same day. ' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:04:51
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:04:44
User opened query 'Per EDC guidelines, NO should be selected if Day 0 and Day 1 are performed the same day. ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:08:00
User closed query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:08:00
Query 'Data is required. Please complete.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:34:57
Query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:34:54
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:34:50
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:34:50
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:34:50
User opened query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:41
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:27
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:29

US3832014

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'please remote date, enter NO' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:08:05
Query 'please remote date, enter NO' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:34:59
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:34:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:34:50
	(b) (4)	
User opened query 'please remote date, enter NO' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:54
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:27
User entered '31 Jul 2020'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:29
	(b) (4)	

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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)	27 Oct 2020 16:13:25
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered '31 Jul 2020'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered '14:30'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 14:30'	System	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered 'Right Arm (RIGHT ARM)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered 'ONCE'	System	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:06
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:13:02

US3832014

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:06
User entered '31 Jul 2020'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:13:02

US3832014

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:06
User entered '14:24'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:13:02

US3832014

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 14:24'	System	01 Aug 2020 22:13:02

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:38
User entered '31 Jul 2020'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:13:25

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:29

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:25

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:38
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:13:25

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:38
User entered '14:23'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:13:25

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 14:23'	System	01 Aug 2020 22:13:25

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:29

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:25

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:20:10
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:20:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:38
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:25

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:20:10
	(b) (4)	
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:20:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:38
User entered '14:23'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:25
	(b) (4)	

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:20:10
User entered '31 Jul 2020 14:23'	System	01 Aug 2020 22:13:25

US3832014

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:49
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:13:30

US3832014

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 22:13:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 14:50'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 17:20'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 18:15'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 2'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:38:42', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered 'Yes (Y)'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:38:56', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered '98.9'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:39:07', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered 'Yes (Y)'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

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 'Subject contacted for Day 8 safety call. Subject taking percocet PRN for pain as baseline therapy. Subject denied taking any additional medications for pain or fever.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 08:38:47
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)	24 Aug 2020 17:16:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:39:20', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered '1'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:39:20', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered '0'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:39:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered '02 Aug 2020 10:39'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 3'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:00:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '04085e4d-35c8-4920-8318-955917f2c60f'	System	02 Aug 2020 16:01:05
User entered 'Yes (Y)'	System	02 Aug 2020 16:01:05

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:00:44', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '04085e4d-35c8-4920-8318-955917f2c60f'	System	02 Aug 2020 16:01:05
User entered '98.3'	System	02 Aug 2020 16:01:05

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:00:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '04085e4d-35c8-4920-8318-955917f2c60f'	System	02 Aug 2020 16:01:05
User entered 'No (N)'	System	02 Aug 2020 16:01:05

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:00:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '04085e4d-35c8-4920-8318-955917f2c60f'	System	02 Aug 2020 16:01:05
User entered '02 Aug 2020 12:00'	System	02 Aug 2020 16:01:05

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 4'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 5'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 6'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 7'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 14:50'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 17:20'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 18:15'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 2'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

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 (40f8709ae304b723)', Time: '2020-08-02T10:42:07', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b3e58f67-5903-4b66-b26d-6ae4634c0cfc'	System	02 Aug 2020 14:42:25
User entered 'None (1)'	System	02 Aug 2020 14:42:25

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:42:11', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b3e58f67-5903-4b66-b26d-6ae4634c0cfc'	System	02 Aug 2020 14:42:25
User entered 'No (N)'	System	02 Aug 2020 14:42:25

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:42:14', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b3e58f67-5903-4b66-b26d-6ae4634c0cfc'	System	02 Aug 2020 14:42:25
User entered 'No (N)'	System	02 Aug 2020 14:42:25

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

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 (40f8709ae304b723)', Time: '2020-08-02T10:42:18', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b3e58f67-5903-4b66-b26d-6ae4634c0cfc'	System	02 Aug 2020 14:42:25
User entered 'None (1)'	System	02 Aug 2020 14:42:25

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:42:23', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b3e58f67-5903-4b66-b26d-6ae4634c0cfc'	System	02 Aug 2020 14:42:25
User entered '02 Aug 2020 10:42'	System	02 Aug 2020 14:42:25

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 3'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

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 (40f8709ae304b723)', Time: '2020-08-02T12:01:02', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '79e4cb37-56e0-4121-8022-500f065b28d8'	System	02 Aug 2020 16:01:17
User entered 'None (1)'	System	02 Aug 2020 16:01:17

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:05', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '79e4cb37-56e0-4121-8022-500f065b28d8'	System	02 Aug 2020 16:01:17
User entered 'No (N)'	System	02 Aug 2020 16:01:17

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:08', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '79e4cb37-56e0-4121-8022-500f065b28d8'	System	02 Aug 2020 16:01:17
User entered 'No (N)'	System	02 Aug 2020 16:01:17

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

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 (40f8709ae304b723)', Time: '2020-08-02T12:01:11', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '79e4cb37-56e0-4121-8022-500f065b28d8'	System	02 Aug 2020 16:01:17
User entered 'None (1)'	System	02 Aug 2020 16:01:17

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:15', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '79e4cb37-56e0-4121-8022-500f065b28d8'	System	02 Aug 2020 16:01:17
User entered '02 Aug 2020 12:01'	System	02 Aug 2020 16:01:17

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 4'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 5'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 6'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 7'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 14:50'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 17:20'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 18:15'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 2'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:40:47', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:40:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:40:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:40:57', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:41:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:41:02', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

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 (40f8709ae304b723)', Time: '2020-08-02T10:41:06', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'No (N)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:41:10', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered '02 Aug 2020 10:41'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 3'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:20', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:23', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:25', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:30', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:32', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

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 (40f8709ae304b723)', Time: '2020-08-02T12:01:38', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'No (N)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered '02 Aug 2020 12:01'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 4'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 5'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 6'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 7'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:17
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	07 Aug 2020 18:51:46

US3832014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:17
User entered '07 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	07 Aug 2020 18:51:46

US3832014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:17
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	07 Aug 2020 18:51:46

US3832014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:17
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	07 Aug 2020 18:51:46

US3832014

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:23
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	07 Aug 2020 18:51:50

US3832014

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 18:51:50

US3832014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:43
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Aug 2020 16:28:33

US3832014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:43
User entered '17 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Aug 2020 16:28:33

US3832014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:43
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Aug 2020 16:28:33

US3832014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:43
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Aug 2020 16:28:33

US3832014

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Aug 2020 16:28:18

US3832014

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:28:18

US3832014

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	21 Aug 2020 13:48:12

US3832014

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	21 Aug 2020 13:48:12

US3832014

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	21 Aug 2020 13:48:12

US3832014

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	21 Aug 2020 13:48:12

US3832014

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	21 Aug 2020 13:48:00

US3832014

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 13:48:00

US3832014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	28 Aug 2020 16:21:18

US3832014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	28 Aug 2020 16:21:18

US3832014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4) (b) (4)	28 Aug 2020 16:21:18

US3832014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	28 Aug 2020 16:21:18

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '11:48'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:48'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '14'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:39:49
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Sep 2020 23:39:49
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:39:48
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 17:00:55
User entered '163'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '93'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '12:43'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:43'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '69'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '16'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:39:49
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Sep 2020 23:39:49
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:39:48
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 17:00:55
User entered '162'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '99'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:05:22

US3832014

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:05:22

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Alyssa-Kay Peay (b) (4)	28 Aug 2020 16:21:41
	(b) (4)	

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '12:13'	Alyssa-Kay Peay (b) (4) (b) (4)	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:13'	System	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Alyssa-Kay Peay (b) (4)	28 Aug 2020 16:21:41
	(b) (4)	

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:05:38

US3832014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:05:38

US3832014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:06'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:05:38

US3832014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:06'	System	16 Sep 2020 17:05:38

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:05:51

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:29

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:51

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:05:51

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:03'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:05:51

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:03'	System	16 Sep 2020 17:05:51

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:29

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:51

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:19:49
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:51

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:19:49
User entered '12:03'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:51

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:19:49
User entered '28 Aug 2020 12:03'	System	16 Sep 2020 17:05:51

US3832014

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	07 Sep 2020 13:40:42
	(b) (4)	

US3832014

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 13:40:42

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:48:38', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'f4a8e7ee-7a48-431e-a7cf-1d3c4ac4e23e'	System	28 Aug 2020 18:49:07
User entered 'Yes (Y)'	System	28 Aug 2020 18:49:07

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:48:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'f4a8e7ee-7a48-431e-a7cf-1d3c4ac4e23e'	System	28 Aug 2020 18:49:07
User entered '98.6'	System	28 Aug 2020 18:49:07

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:48:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'f4a8e7ee-7a48-431e-a7cf-1d3c4ac4e23e'	System	28 Aug 2020 18:49:07
User entered 'No (N)'	System	28 Aug 2020 18:49:07

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:03', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'f4a8e7ee-7a48-431e-a7cf-1d3c4ac4e23e'	System	28 Aug 2020 18:49:07
User entered '28 Aug 2020 14:49'	System	28 Aug 2020 18:49:07

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:33'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:03'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:21:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '49beb6a9-bcbf-4793-a31c-7ff116c1b854'	System	28 Aug 2020 20:21:59
User entered 'Yes (Y)'	System	28 Aug 2020 20:21:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:21:48', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '49beb6a9-bcbf-4793-a31c-7ff116c1b854'	System	28 Aug 2020 20:21:59
User entered '98.4'	System	28 Aug 2020 20:21:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:21:53', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '49beb6a9-bcbf-4793-a31c-7ff116c1b854'	System	28 Aug 2020 20:21:59
User entered 'No (N)'	System	28 Aug 2020 20:21:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:21:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '49beb6a9-bcbf-4793-a31c-7ff116c1b854'	System	28 Aug 2020 20:21:59
User entered '28 Aug 2020 16:21'	System	28 Aug 2020 20:21:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 2'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:20:35', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '930bc623-62b0-4b5b-b6aa-f0342e3793be'	System	30 Aug 2020 01:20:53
User entered 'Yes (Y)'	System	30 Aug 2020 01:20:53

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:20:42', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '930bc623-62b0-4b5b-b6aa-f0342e3793be'	System	30 Aug 2020 01:20:53
User entered '98.6'	System	30 Aug 2020 01:20:53

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:20:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '930bc623-62b0-4b5b-b6aa-f0342e3793be'	System	30 Aug 2020 01:20:53
User entered 'No (N)'	System	30 Aug 2020 01:20:53

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:20:50', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '930bc623-62b0-4b5b-b6aa-f0342e3793be'	System	30 Aug 2020 01:20:53
User entered '29 Aug 2020 21:20'	System	30 Aug 2020 01:20:53

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 3'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:00:31', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a5c2d42c-b5f7-44ae-8a5f-46f648722088'	System	30 Aug 2020 16:00:56
User entered 'Yes (Y)'	System	30 Aug 2020 16:00:56

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:00:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a5c2d42c-b5f7-44ae-8a5f-46f648722088'	System	30 Aug 2020 16:00:56
User entered '98.6'	System	30 Aug 2020 16:00:56

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:00:42', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a5c2d42c-b5f7-44ae-8a5f-46f648722088'	System	30 Aug 2020 16:00:56
User entered 'No (N)'	System	30 Aug 2020 16:00:56

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:00:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a5c2d42c-b5f7-44ae-8a5f-46f648722088'	System	30 Aug 2020 16:00:56
User entered '30 Aug 2020 12:00'	System	30 Aug 2020 16:00:56

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 4'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:16:56', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '67c5c1b6-c2f1-456e-8960-1a56eca11219'	System	31 Aug 2020 16:32:49
User entered 'Yes (Y)'	System	31 Aug 2020 16:32:49

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:04', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '67c5c1b6-c2f1-456e-8960-1a56eca11219'	System	31 Aug 2020 16:32:49
User entered '98.9'	System	31 Aug 2020 16:32:49

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:08', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '67c5c1b6-c2f1-456e-8960-1a56eca11219'	System	31 Aug 2020 16:32:49
User entered 'No (N)'	System	31 Aug 2020 16:32:49

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:12', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '67c5c1b6-c2f1-456e-8960-1a56eca11219'	System	31 Aug 2020 16:32:49
User entered '31 Aug 2020 12:17'	System	31 Aug 2020 16:32:49

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 5'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:07:25', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '409ffa64-0dae-46fc-a2c3-d6cd7392e9b1'	System	01 Sep 2020 16:08:03
User entered 'Yes (Y)'	System	01 Sep 2020 16:08:03

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:07:39', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '409ffa64-0dae-46fc-a2c3-d6cd7392e9b1'	System	01 Sep 2020 16:08:03
User entered '97.2'	System	01 Sep 2020 16:08:03

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:07:56', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '409ffa64-0dae-46fc-a2c3-d6cd7392e9b1'	System	01 Sep 2020 16:08:03
User entered 'No (N)'	System	01 Sep 2020 16:08:03

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '409ffa64-0dae-46fc-a2c3-d6cd7392e9b1'	System	01 Sep 2020 16:08:03
User entered '01 Sep 2020 12:08'	System	01 Sep 2020 16:08:03

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 6'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:08', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c5e512a-c8fe-4d9f-8ee7-095ac92a3c19'	System	03 Sep 2020 14:57:27
User entered 'Yes (Y)'	System	03 Sep 2020 14:57:27

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:14', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c5e512a-c8fe-4d9f-8ee7-095ac92a3c19'	System	03 Sep 2020 14:57:27
User entered '98.8'	System	03 Sep 2020 14:57:27

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:19', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c5e512a-c8fe-4d9f-8ee7-095ac92a3c19'	System	03 Sep 2020 14:57:27
User entered 'No (N)'	System	03 Sep 2020 14:57:27

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:23', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c5e512a-c8fe-4d9f-8ee7-095ac92a3c19'	System	03 Sep 2020 14:57:27
User entered '03 Sep 2020 10:57'	System	03 Sep 2020 14:57:27

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 7'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:01:29', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '21596e56-a12f-4f96-af3a-542e35a3ab3a'	System	03 Sep 2020 16:03:32
User entered 'Yes (Y)'	System	03 Sep 2020 16:03:32

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:01:45', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '21596e56-a12f-4f96-af3a-542e35a3ab3a'	System	03 Sep 2020 16:03:32
User entered '98.6'	System	03 Sep 2020 16:03:32

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:01:52', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '21596e56-a12f-4f96-af3a-542e35a3ab3a'	System	03 Sep 2020 16:03:32
User entered 'No (N)'	System	03 Sep 2020 16:03:32

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:01:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '21596e56-a12f-4f96-af3a-542e35a3ab3a'	System	03 Sep 2020 16:03:32
User entered '03 Sep 2020 12:01'	System	03 Sep 2020 16:03:32

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:15', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ab7a1f21-b05a-4239-a06c-5124f79cfac7'	System	28 Aug 2020 18:49:38
User entered 'None (1)'	System	28 Aug 2020 18:49:38

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:18', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ab7a1f21-b05a-4239-a06c-5124f79cfac7'	System	28 Aug 2020 18:49:38
User entered 'No (N)'	System	28 Aug 2020 18:49:38

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:21', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ab7a1f21-b05a-4239-a06c-5124f79cfac7'	System	28 Aug 2020 18:49:38
User entered 'No (N)'	System	28 Aug 2020 18:49:38

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:29', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ab7a1f21-b05a-4239-a06c-5124f79cfac7'	System	28 Aug 2020 18:49:38
User entered 'None (1)'	System	28 Aug 2020 18:49:38

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:34', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ab7a1f21-b05a-4239-a06c-5124f79cfac7'	System	28 Aug 2020 18:49:38
User entered '28 Aug 2020 14:49'	System	28 Aug 2020 18:49:38

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:33'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:03'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:04', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '050cfbae-e0fb-490a-8a80-10ca906d98b4'	System	28 Aug 2020 20:22:25
User entered 'None (1)'	System	28 Aug 2020 20:22:25

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:08', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '050cfbae-e0fb-490a-8a80-10ca906d98b4'	System	28 Aug 2020 20:22:25
User entered 'No (N)'	System	28 Aug 2020 20:22:25

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:10', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '050cfbae-e0fb-490a-8a80-10ca906d98b4'	System	28 Aug 2020 20:22:25
User entered 'No (N)'	System	28 Aug 2020 20:22:25

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:15', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '050cfbae-e0fb-490a-8a80-10ca906d98b4'	System	28 Aug 2020 20:22:25
User entered 'None (1)'	System	28 Aug 2020 20:22:25

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:22', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '050cfbae-e0fb-490a-8a80-10ca906d98b4'	System	28 Aug 2020 20:22:25
User entered '28 Aug 2020 16:22'	System	28 Aug 2020 20:22:25

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 2'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

[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 (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:11', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cc9a0be-eede-4211-8f45-b792cc863798'	System	30 Aug 2020 01:21:33
User entered 'None (1)'	System	30 Aug 2020 01:21:33

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:15', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cc9a0be-eede-4211-8f45-b792cc863798'	System	30 Aug 2020 01:21:33
User entered 'No (N)'	System	30 Aug 2020 01:21:33

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:18', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cc9a0be-eede-4211-8f45-b792cc863798'	System	30 Aug 2020 01:21:33
User entered 'No (N)'	System	30 Aug 2020 01:21:33

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:24', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cc9a0be-eede-4211-8f45-b792cc863798'	System	30 Aug 2020 01:21:33
User entered 'None (1)'	System	30 Aug 2020 01:21:33

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:29', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cc9a0be-eede-4211-8f45-b792cc863798'	System	30 Aug 2020 01:21:33
User entered '29 Aug 2020 21:21'	System	30 Aug 2020 01:21:33

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 3'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-30T12:00:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0aab37ba-813c-47fb-b9ce-e183cbe6e936'	System	30 Aug 2020 16:01:35
User entered 'None (1)'	System	30 Aug 2020 16:01:35

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:02', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0aab37ba-813c-47fb-b9ce-e183cbe6e936'	System	30 Aug 2020 16:01:35
User entered 'No (N)'	System	30 Aug 2020 16:01:35

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:06', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0aab37ba-813c-47fb-b9ce-e183cbe6e936'	System	30 Aug 2020 16:01:35
User entered 'No (N)'	System	30 Aug 2020 16:01:35

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:09', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0aab37ba-813c-47fb-b9ce-e183cbe6e936'	System	30 Aug 2020 16:01:35
User entered 'None (1)'	System	30 Aug 2020 16:01:35

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:12', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0aab37ba-813c-47fb-b9ce-e183cbe6e936'	System	30 Aug 2020 16:01:35
User entered '30 Aug 2020 12:01'	System	30 Aug 2020 16:01:35

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 4'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:17', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '382806c5-8157-406a-948e-02cc37a4e544'	System	01 Sep 2020 16:07:09
User entered 'None (1)'	System	01 Sep 2020 16:07:09

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:21', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '382806c5-8157-406a-948e-02cc37a4e544'	System	01 Sep 2020 16:07:09
User entered 'No (N)'	System	01 Sep 2020 16:07:09

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:24', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '382806c5-8157-406a-948e-02cc37a4e544'	System	01 Sep 2020 16:07:09
User entered 'No (N)'	System	01 Sep 2020 16:07:09

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:30', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '382806c5-8157-406a-948e-02cc37a4e544'	System	01 Sep 2020 16:07:09
User entered 'None (1)'	System	01 Sep 2020 16:07:09

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:33', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '382806c5-8157-406a-948e-02cc37a4e544'	System	01 Sep 2020 16:07:09
User entered '31 Aug 2020 12:17'	System	01 Sep 2020 16:07:09

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 5'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:14', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '18cc5664-ce4c-44b9-9352-bf8e77a3aae1'	System	01 Sep 2020 16:08:43
User entered 'None (1)'	System	01 Sep 2020 16:08:43

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:18', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '18cc5664-ce4c-44b9-9352-bf8e77a3aae1'	System	01 Sep 2020 16:08:43
User entered 'No (N)'	System	01 Sep 2020 16:08:43

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '18cc5664-ce4c-44b9-9352-bf8e77a3aae1'	System	01 Sep 2020 16:08:43
User entered 'No (N)'	System	01 Sep 2020 16:08:43

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '18cc5664-ce4c-44b9-9352-bf8e77a3aae1'	System	01 Sep 2020 16:08:43
User entered 'None (1)'	System	01 Sep 2020 16:08:43

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:40', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '18cc5664-ce4c-44b9-9352-bf8e77a3aae1'	System	01 Sep 2020 16:08:43
User entered '01 Sep 2020 12:08'	System	01 Sep 2020 16:08:43

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 6'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'd555d96d-a8c6-44be-b77b-cf4b89a294ab'	System	03 Sep 2020 14:57:44
User entered 'None (1)'	System	03 Sep 2020 14:57:44

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:32', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'd555d96d-a8c6-44be-b77b-cf4b89a294ab'	System	03 Sep 2020 14:57:44
User entered 'No (N)'	System	03 Sep 2020 14:57:44

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:35', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'd555d96d-a8c6-44be-b77b-cf4b89a294ab'	System	03 Sep 2020 14:57:44
User entered 'No (N)'	System	03 Sep 2020 14:57:44

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:39', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'd555d96d-a8c6-44be-b77b-cf4b89a294ab'	System	03 Sep 2020 14:57:44
User entered 'None (1)'	System	03 Sep 2020 14:57:44

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'd555d96d-a8c6-44be-b77b-cf4b89a294ab'	System	03 Sep 2020 14:57:44
User entered '03 Sep 2020 10:57'	System	03 Sep 2020 14:57:44

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 7'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-09-03T12:01:59', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c6f48be-c08a-495c-94d1-51a0e534f737'	System	03 Sep 2020 16:03:57
User entered 'None (1)'	System	03 Sep 2020 16:03:57

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:03', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c6f48be-c08a-495c-94d1-51a0e534f737'	System	03 Sep 2020 16:03:57
User entered 'No (N)'	System	03 Sep 2020 16:03:57

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:05', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c6f48be-c08a-495c-94d1-51a0e534f737'	System	03 Sep 2020 16:03:57
User entered 'No (N)'	System	03 Sep 2020 16:03:57

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:08', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c6f48be-c08a-495c-94d1-51a0e534f737'	System	03 Sep 2020 16:03:57
User entered 'None (1)'	System	03 Sep 2020 16:03:57

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:12', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c6f48be-c08a-495c-94d1-51a0e534f737'	System	03 Sep 2020 16:03:57
User entered '03 Sep 2020 12:02'	System	03 Sep 2020 16:03:57

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:49', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:50:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-28T14:50:03', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'No (N)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:50:06', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered '28 Aug 2020 14:50'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:33'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:03'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:32', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:48', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:59', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'No (N)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:23:05', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered '28 Aug 2020 16:23'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 2'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:49', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:52', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:59', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'No (N)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:22:02', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered '29 Aug 2020 21:22'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 3'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:17', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:19', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:21', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:24', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:26', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:34', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'No (N)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered '30 Aug 2020 12:01'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 4'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:40', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:42', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:50', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:54', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-08-31T12:18:05', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'No (N)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:18:09', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered '31 Aug 2020 12:18'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 5'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:01', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:11', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:18', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:25', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:34', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'No (N)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:43', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered '01 Sep 2020 12:09'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 6'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:48', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:53', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:56', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-09-03T10:58:04', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'No (N)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:58:06', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered '03 Sep 2020 10:58'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 7'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:17', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:26', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:32', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:34', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:43', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'No (N)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered '03 Sep 2020 12:02'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	07 Sep 2020 13:50:13
	(b) (4)	

US3832014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	07 Sep 2020 13:50:13

US3832014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	07 Sep 2020 13:50:13

US3832014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alyssa-Kay Peay (b) (4)	07 Sep 2020 13:50:13
	(b) (4)	

US3832014

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	07 Sep 2020 13:50:18
	(b) (4)	

US3832014

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 13:50:18

US3832014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	17 Sep 2020 12:21:39

US3832014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Ashten Sheriff (b) (4) (b) (4)	17 Sep 2020 12:21:39

US3832014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ashten Sheriff (b) (4) (b) (4)	17 Sep 2020 12:21:39

US3832014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	17 Sep 2020 12:21:39

US3832014

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	17 Sep 2020 12:21:43

US3832014

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 12:21:43

US3832014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 18:19:54

US3832014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 18:19:54

US3832014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Sep 2020 18:19:54

US3832014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 18:19:54

US3832014

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 18:19:57

US3832014

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 18:19:57

US3832014

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:03

US3832014

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:03

US3832014

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:03

US3832014

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	01 Oct 2020 15:10:03

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '10:38'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '1 Oct 2020 10:38'	System	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '16'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '162'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '100'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:56

US3832014

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:10:56

US3832014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:11:16

US3832014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:11:16

US3832014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:53'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:11:16

US3832014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '1 Oct 2020 10:53'	System	01 Oct 2020 15:11:16

US3832014

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	01 Oct 2020 15:11:21

US3832014

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:11:21

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 64'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[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 (28d2d8b6222b8d66)', Time: '2020-10-02T08:52:38', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '45ec17d8-4a5b-440f-ad64-1d2ad24f1c1c'	System	02 Oct 2020 12:52:55
User entered 'No (N)'	System	02 Oct 2020 12:52:55

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Have you been exposed to someone with 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 (28d2d8b6222b8d66)', Time: '2020-10-02T08:52:48', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '45ec17d8-4a5b-440f-ad64-1d2ad24f1c1c'	System	02 Oct 2020 12:52:55
User entered 'No (N)'	System	02 Oct 2020 12:52:55

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-02T08:52:52', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '45ec17d8-4a5b-440f-ad64-1d2ad24f1c1c'	System	02 Oct 2020 12:52:55
User entered '02 Oct 2020 08:52:52'	System	02 Oct 2020 12:52:55

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '30 Sep 2020 00:01'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '04 Oct 2020 23:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 71'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[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 (28d2d8b6222b8d66)', Time: '2020-10-09T14:40:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4fd701fe-a1ac-4b31-bcf6-6162a0b772d1'	System	09 Oct 2020 18:41:05
User entered 'No (N)'	System	09 Oct 2020 18:41:05

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

Have you been exposed to someone with 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 (28d2d8b6222b8d66)', Time: '2020-10-09T14:40:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4fd701fe-a1ac-4b31-bcf6-6162a0b772d1'	System	09 Oct 2020 18:41:05
User entered 'No (N)'	System	09 Oct 2020 18:41:05

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-09T14:40:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4fd701fe-a1ac-4b31-bcf6-6162a0b772d1'	System	09 Oct 2020 18:41:05
User entered '09 Oct 2020 14:40:58'	System	09 Oct 2020 18:41:05

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '07 Oct 2020 00:01'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '11 Oct 2020 23:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 78'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[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 (28d2d8b6222b8d66)', Time: '2020-10-16T09:40:26', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0a681bf6-4ff3-4b36-8497-400362c68070'	System	16 Oct 2020 13:40:42
User entered 'No (N)'	System	16 Oct 2020 13:40:42

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

Have you been exposed to someone with 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 (28d2d8b6222b8d66)', Time: '2020-10-16T09:40:31', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0a681bf6-4ff3-4b36-8497-400362c68070'	System	16 Oct 2020 13:40:42
User entered 'No (N)'	System	16 Oct 2020 13:40:42

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-16T09:40:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0a681bf6-4ff3-4b36-8497-400362c68070'	System	16 Oct 2020 13:40:42
User entered '16 Oct 2020 09:40:37'	System	16 Oct 2020 13:40:42

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '14 Oct 2020 00:01'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '18 Oct 2020 23:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 92'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[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 (28d2d8b6222b8d66)', Time: '2020-10-28T01:18:40', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'bff1ed39-366f-4b89-9569-cdce85d3552c'	System	28 Oct 2020 05:18:53
User entered 'No (N)'	System	28 Oct 2020 05:18:53

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Have you been exposed to someone with 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 (28d2d8b6222b8d66)', Time: '2020-10-28T01:18:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'bff1ed39-366f-4b89-9569-cdce85d3552c'	System	28 Oct 2020 05:18:53
User entered 'No (N)'	System	28 Oct 2020 05:18:53

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-28T01:18:50', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'bff1ed39-366f-4b89-9569-cdce85d3552c'	System	28 Oct 2020 05:18:53
User entered '28 Oct 2020 01:18:50'	System	28 Oct 2020 05:18:53

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '28 Oct 2020 00:01'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '01 Nov 2020 23:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 99'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

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 (28d2d8b6222b8d66)', Time: '2020-11-06T09:53:38', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '054de2b7-5bd4-4e8b-b635-e466dd680aed'	System	06 Nov 2020 14:53:55
User entered 'No (N)'	System	06 Nov 2020 14:53:55

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

Have you been exposed to someone with 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 (28d2d8b6222b8d66)', Time: '2020-11-06T09:53:44', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '054de2b7-5bd4-4e8b-b635-e466dd680aed'	System	06 Nov 2020 14:53:55
User entered 'No (N)'	System	06 Nov 2020 14:53:55

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-06T09:53:50', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '054de2b7-5bd4-4e8b-b635-e466dd680aed'	System	06 Nov 2020 14:53:55
User entered '06 Nov 2020 09:53:50'	System	06 Nov 2020 14:53:55

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '04 Nov 2020 00:01'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '08 Nov 2020 23:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 106'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[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 (28d2d8b6222b8d66)', Time: '2020-11-11T01:17:09', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'cf6c7f35-6ac2-4a94-bb85-ecae2a681abc'	System	11 Nov 2020 06:17:39
User entered 'No (N)'	System	11 Nov 2020 06:17:39

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

Have you been exposed to someone with 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 (28d2d8b6222b8d66)', Time: '2020-11-11T01:17:23', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'cf6c7f35-6ac2-4a94-bb85-ecae2a681abc'	System	11 Nov 2020 06:17:39
User entered 'No (N)'	System	11 Nov 2020 06:17:39

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-11T01:17:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'cf6c7f35-6ac2-4a94-bb85-ecae2a681abc'	System	11 Nov 2020 06:17:39
User entered '11 Nov 2020 01:17:36'	System	11 Nov 2020 06:17:39

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '11 Nov 2020 00:01'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '15 Nov 2020 23:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 Sep 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 Oct 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Oct 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 Oct 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Oct 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 Oct 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Oct 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 Oct 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[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 (28d2d8b6222b8d66)', Time: '2020-11-22T23:59:42', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '8278b0b6-a13a-41cf-a08e-8cf63a407402'	System	23 Nov 2020 04:59:55
User entered 'No (N)'	System	23 Nov 2020 04:59:55

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Have you been exposed to someone with 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 (28d2d8b6222b8d66)', Time: '2020-11-22T23:59:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '8278b0b6-a13a-41cf-a08e-8cf63a407402'	System	23 Nov 2020 04:59:55
User entered 'No (N)'	System	23 Nov 2020 04:59:55

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-22T23:59:50', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '8278b0b6-a13a-41cf-a08e-8cf63a407402'	System	23 Nov 2020 04:59:55
User entered '22 Nov 2020 23:59:50'	System	23 Nov 2020 04:59:55

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 11:01:15

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	26 Oct 2020 13:27:33
	(b) (4)	

US3832014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '26 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	26 Oct 2020 13:27:33

US3832014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	26 Oct 2020 13:27:33

US3832014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alyssa-Kay Peay (b) (4)	26 Oct 2020 13:27:33
	(b) (4)	

US3832014

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	26 Oct 2020 13:27:38

US3832014

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 13:27:38

US3832014

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Nov 2020 19:54:16

US3832014

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Nov 2020 19:54:16

US3832014

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	24 Nov 2020 19:54:16

US3832014

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	24 Nov 2020 19:54:16

US3832014

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Nov 2020 19:54:21

US3832014

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 19:54:21

US3832014

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:21:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:43:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:08:57

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:00
User entered 'USA-US100-2020-mRNA-1273-P301000003'	System	20 Sep 2020 17:48:56
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 17:48:56

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User closed query 'PV Query: The subject's BP (220/151) was in a range of hypertensive urgency. Please consider updating event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:16:23
Query 'PV Query: The subject's BP (220/151) was in a range of hypertensive urgency. Please consider updating event term accordingly.' answered with 'Term updated ' (Site from Safety).	Danyel Johnson (b) (4)	14 Oct 2020 17:08:49
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Accelerated and malignant hypertension, PT: Hypertensive emergency, LLT: Hypertensive emergency - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 15:41:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 15:41:34
Data point term sent to Coder	System	14 Oct 2020 15:40:39
Coding entries removed.	Danyel Johnson (b) (4)	14 Oct 2020 15:40:22
User entered 'Hypertensive emergency' reason for change: Data Entry Error	Danyel Johnson (b) (4)	14 Oct 2020 15:40:22
User opened query 'PV Query: The subject's BP (220/151) was in a range of hypertensive urgency. Please consider updating event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:17:37
Query 'PV Query: The subject's BP (220/1510) was in a range of hypertensive urgency. Please consider updating event term accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:17:28
User opened query 'PV Query: The subject's BP (220/1510) was in a range of hypertensive urgency. Please consider updating event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:17:23
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\23.0.	Coder Import (b) (4)	18 Sep 2020 17:16:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Sep 2020 17:16:42
Data point term sent to Coder	System	18 Sep 2020 17:15:55

v6.020 DTW (1102)

1493 of 2135

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Worsening of Hypertension'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:34:20
DataPoint Un-verified.	Danyel Johnson (b) (4)	02 Nov 2020 15:58:13
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 15:58:13
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '14 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:34:23
DataPoint Un-verified.	Danyel Johnson (b) (4)	02 Nov 2020 15:58:13
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	02 Nov 2020 15:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '16 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '1'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Hospital admission and discharge dates are prior to the onset of the SAE. Please confirm if there are two separate hospitalizations and if so, please provide the details. If not, please reconcile and update the event onset and end dates. Otherwise, please clarify.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:55:28
Query 'PV Query: Hospital admission and discharge dates are prior to the onset of the SAE. Please confirm if there are two separate hospitalizations and if so, please provide the details. If not, please reconcile and update the event onset and end dates. Otherwise, please clarify.' answered with 'data updated per source' (Site from Safety).	Danyel Johnson (b) (4)	02 Nov 2020 15:58:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User opened query 'PV Query: Hospital admission and discharge dates are prior to the onset of the SAE. Please confirm if there are two separate hospitalizations and if so, please provide the details. If not, please reconcile and update the event onset and end dates. Otherwise, please clarify.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:47:31
User entered '31 Aug 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 14:03:39
User entered '14 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '02 Sep 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 14:03:39
User entered '16 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Sep 2020 17:15:59
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Sep 2020 17:15:27
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:59:25
	(b) (4), (b) (6)	27 Oct 2020 14:32:29
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify. ' answered with 'Conmeds 9-19 are all associated with this event ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	22 Oct 2020 11:42:06
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 02:04:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 17:15:59
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Per the discharge summary, "Her creatinine was slightly compared to 01 Sep 2020 due to probable dehydration from poor oral intake.", please provide creatinine levels or indication of high or low.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 17:04:10
User closed query 'PV Query: Per the discharge summary, the subject has a prior medical history of chronic pain and asthma. Please reconcile and update the medical history accordingly, if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 17:04:09
Query 'PV Query: Per the discharge summary, "Her creatinine was slightly compared to 01 Sep 2020 due to probable dehydration from poor oral intake.", please provide creatinine levels or indication of high or low.' answered with '1.30 was the reported level ref. range is 0.50-0.90' (Site from Safety).	Danyel Johnson (b) (4)	10 Nov 2020 17:34:04
Query 'PV Query: Per the discharge summary, the subject has a prior medical history of chronic pain and asthma. Please reconcile and update the medical history accordingly, if applicable.' answered with 'Per subject report she suffers from COPD and Muscle spasms not Asthma and chronic pain' (Site from Safety).	Danyel Johnson (b) (4)	10 Nov 2020 17:32:53
User closed query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:55:39
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:55:37

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' answered with 'Visit 0 B/P 128/83 7/31/2020 Visit 2 Day 29 B/P 163/93 8/28/2020 Visit 3 Day 57 B/P 162/100' (Site from Safety).	Danyel Johnson (b) (4)	02 Nov 2020 16:02:32
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Data has been added ' (Site from Safety).	Danyel Johnson (b) (4)	02 Nov 2020 15:59:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User opened query 'PV Query: Per the discharge summary, "Her creatinine was slightly compared to 01 Sep 2020 due to probable dehydration from poor oral intake.", please provide creatineine levels or indication of high or low.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:47:54
User opened query 'PV Query: Per the discharge summary, the subject has a prior medical history of chronic pain and asthma. Please reconcile and update the medical history accordingly, if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:47:39
User opened query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:47:14
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:47:00

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: The subject was reportedly found at ER with shingles. Please consider reporting AE/SAE Shingles.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:54:24
User closed query 'PV Query: The subject was reportedly found at ER with shingles. Please clarify confirmation of the diagnostic, extent and treatment.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:54:22
User closed query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:54:19
User closed query 'PV Query: At ER, BP was found to be 222/151. Please clarify whether the patient had clinical signs associated to the increased BP.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:54:16
User closed query 'PV Query: Please clarify the reason for subject's emergency room visit.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:54:13
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:54:09
Query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' answered with 'Visit 0 B/P 128/83 7/31/2020 Visit 2 Day 29 B/P 163/93 8/28/2020 Visit 3 Day 57 B/P 162/100 ' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:12:49
Query 'PV Query: The subject was reportedly found at ER with shingles. Please consider reporting AE/SAE Shingles.' answered with 'Updated per review of hospital admission and discharge records, No report of shingles noted' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:07:29

v6.020 DTW (1102)

1527 of 2135

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The subject was reportedly found at ER with shingles. Please clarify confirmation of the diagnostic, extent and treatment.' answered with 'Updated per review of hospital admission and discharge records, No report of shingles noted' (Site from Safety).	Danyel Johnson (b) (4)	15 Oct 2020 14:07:23
Query 'PV Query: At ER, BP was found to be 222/151. Please clarify whether the patient had clinical signs associated to the increased BP.' answered with 'Updated per review of hospital admission and discharge records ' (Site from Safety).	Danyel Johnson (b) (4)	15 Oct 2020 14:06:41
Query 'PV Query: Please clarify the reason for subject's emergency room visit.' answered with 'Updated per review of hospital admission and discharge records ' (Site from Safety).	Danyel Johnson (b) (4)	15 Oct 2020 14:06:36
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Updated per review of hospital admission and discharge records' (Site from Safety).	Danyel Johnson (b) (4)	15 Oct 2020 14:05:56

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Based on review of medical records received on 01 Oct 2020 the following information has been updated Admission date 31 Aug 2020 Discharge date 02 Sep 2020 Admin Diagnosis Hypertensive Emergency (Likely caused by acute back pain which resulted in hypertension, tachycardia and anxiety). 08/31/2020 Subject was seen in the ER early in the day for abdominal pain. The subject was treated with morphine for pain and had a CT scan of abdomen and pelvis which were both found to be within normal limits with no specific cause for pain. The subject later returned that day with severe headache and left upper quadrant abdominal pain. The subject was found on the bathroom floor. It is unclear how she ended up on the bathroom floor. Vitals obtained 08/31/2020 at 1402 by ER triage with the following findings: HR 113 B/P 242/136. Subject was admitted at this time point with nondescript abdominal pain, with noted negative x-ray and CT. Concern was noted that this episode may be representative of withdrawal since the subject has not been on her pain medication for the better part of the day. The subject remains confused and given the hypertensive emergency, stroke has been noted as a differential, but fortunately she has no acute unilateral deficits. Subject was admitted to ICU with the following plan: Hypertensive Emergency: Started on a Cardene drip and an Echo. Echo WNL Altered Mental Status: Stat CT of head WNL Hyperglycemia: Monitor with collection of a HgA1c Elevated brain natriuretic peptide Level: Continue to monitor Abdominal Pain: CT completed WNL with no acute pathology. All collected information and comments have been updated.' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 14:05:04
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:16:33

v6.020 DTW (1102)

1529 of 2135

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Sent via email 10/14/2020' (Site from Safety).	Danyel Johnson (b) (4)	14 Oct 2020 17:41:14
User opened query 'PV Query: The subject was reportedly found at ER with shingles. Please consider reporting AE/SAE Shingles.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:17:52
User opened query 'PV Query: The subject was reportedly found at ER with shingles. Please clarify confirmation of the diagnostic, extent and treatment.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:17:05
User opened query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:16:54
User opened query 'PV Query: At ER, BP was found to be 222/151. Please clarify whether the patient had clinical signs associated to the increased BP.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 15:41:56
User opened query 'PV Query: Please clarify the reason for subject's emergency room visit.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 15:41:41
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 15:41:29
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 15:41:10

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Narrative](#)

Audit	User	Time (GMT)
User entered 'At Day 50 safety call, subject reported being hospitalized from 14Sep2020 thru 16Sep2020 due to worsening of hypertension. Subject also reports AE of shingles. Subject states she went to ER on 14Sep2020 and was diagnosed with shingles. She reports her blood pressure was 222/151 mmHg. Subject reports being admitted to hospital for observation due to elevated blood pressure reading. She reports receiving several medications but is unable to recall the names at time of contact. Subject reports being discharged in stable condition on 16Sep2020. Subject was instructed to come to office as soon as possible to complete medical record release form. Will follow up upon receipt and review of medical records.'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'per hospital record discharge summary, subject had acute back pain which led to HTN crisis. please confirm if this should be captured as AE also and update as needed.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:54:01
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Mental disorders NEC, PT: Mental status changes, LLT: Mental status changes - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:30:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	15 Oct 2020 16:30:31
Data point term sent to Coder	System	15 Oct 2020 15:22:49
User entered 'Altered Mental status'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13
	(b) (4)	

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13
	(b) (4)	

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:34:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:34:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:34:06
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:22:13
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:34:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:34:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:34:06
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:22:13
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:34:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:34:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:34:06
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:22:13
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[None](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	10 Nov 2020 17:36:43
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	15 Oct 2020 15:34:06
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Oct 2020 15:22:13
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:16:10
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Reviewed and updated per source' (Site from DM).	Danyel Johnson (b) (4)	10 Nov 2020 17:37:57
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4)	10 Nov 2020 17:36:43
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:31:41
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:34:06
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:34:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:34:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:34:06
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:22:13
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:21:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 16:05:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 16:05:52
Data point term sent to Coder	System	15 Oct 2020 15:27:58
User entered 'Hyperglycemia'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46
	(b) (4)	

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46
	(b) (4)	

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46
	(b) (4)	

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:16:21
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Reviewed and updated per source' (Site from DM).	Danyel Johnson (b) (4)	10 Nov 2020 17:38:37
User entered '0' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:38:22
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:32:09
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Oct 2020 15:34:26
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:34:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Oct 2020 15:27:46
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	10 Nov 2020 17:38:22
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46
	(b) (4)	

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:21:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLG: Metabolic, nutritional and blood gas investigations, HLT: Metabolism tests NEC, PT: Brain natriuretic peptide increased, LLT: Brain natriuretic peptide increased - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:27:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:27:26
Data point term sent to Coder	System	15 Oct 2020 15:33:09
User entered 'Elevated brain natriuretic peptide level'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28
	(b) (4)	

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:36:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:36:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:36:06
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:32:28
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:36:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:36:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:36:06
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:32:28
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:36:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:36:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:36:06
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:32:28
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[None](#)

Audit	User	Time (GMT)
User entered '1'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:21:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:06:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:06:20
Data point term sent to Coder	System	15 Oct 2020 15:34:10
User entered 'Abdominal pain'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23
	(b) (4)	

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[None](#)

Audit	User	Time (GMT)
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:00:53
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'per log line 2 the data has been added' (Site from DM).	Danyel Johnson (b) (4)	10 Nov 2020 17:40:50
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:32:25
User entered '1'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:21:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 15:33:23

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:21:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:47:51
User closed query 'Per ETRTR: Please add Medication and dosing provided for SAE Hypertensive Emergency, thanks.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 17:06:17
Query 'Per ETRTR: Please add Medication and dosing provided for SAE Hypertensive Emergency, thanks.' answered with 'Reviewed and added ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:40:35
User opened query 'Per ETRTR: Please add Medication and dosing provided for SAE Hypertensive Emergency, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:38:05
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:19:29

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM BROMIDE, PRODUCTSYNONYM: SPIRIVA HANDIHALER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 11:23:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 11:23:10
Data point term sent to Coder	System	06 Aug 2020 11:22:49
User entered 'Spiriva Handihaler'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'COPD- Chronic Obstructive Pulmonary Disease'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '5'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 12:51:43
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	06 Aug 2020 11:22:05
User entered 'un UNK 2013'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: COMBIVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 14:48:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 14:48:08
Data point term sent to Coder	System	06 Aug 2020 11:23:49
User entered 'Combivent'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Chronic Obstructive Pulmonary Disease'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '100/20'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:12:52
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	06 Aug 2020 11:23:31
User entered 'un UNK 2013'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 11:27:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 11:27:12
Data point term sent to Coder	System	06 Aug 2020 11:25:50
User entered 'Clonidine'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0.3'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:12:58
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	06 Aug 2020 11:25:14
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	24 Aug 2020 17:10:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 17:10:40
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Aug 2020 11:25:14
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL HYDROCHLORIDE, PRODUCTSYNONYM: XOPENEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 10:31:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 10:31:06
Data point term sent to Coder	System	06 Aug 2020 11:28:50
User entered 'Xopenex'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Chronic Obstructive Pulmonary Disease'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '1.25'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:13:20
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	06 Aug 2020 11:28:05
User entered 'un UNK 2013'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Per MM, Please review this medication and route. As per EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)'. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:30:48
Query 'Per MM, Please review this medication and route. As per EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)'. Please update as appropriate.' answered with 'Flovent is an inhaled corticosteroid. Protocol prohibits systemic steroid use. Per Protocol Flovent is an allowable medication ' (Site from DM).	Danyel Johnson (b) (4)	23 Sep 2020 16:43:04
User opened query 'Per MM, Please review this medication and route. As per EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)'. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:05:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLOVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 23:26:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 23:26:13
Data point term sent to Coder	System	06 Aug 2020 11:37:51
User entered 'Flovent'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Chronic Obstructive Pulmonary Disease'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '88'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:11:56
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	06 Aug 2020 11:37:46
User entered 'un UNK 2013'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE, PRODUCTSYNONYM: HYDROMET [HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 07:46:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 07:46:32
Data point term sent to Coder DataPoint Un-verified.	System	13 Nov 2020 13:29:46
	Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
	(b) (4)	
Coding entries removed.	Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
	(b) (4)	
User entered 'HYDROMET 5 mg-1.5 mg/5 mL oral syrup [HYDROCODONE/HOMATROPINE]' reason for change: Per Query Resolution	Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE, PRODUCTSYNONYM: HYDROMET [HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 17:32:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 17:32:49

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:10:49
Data point term sent to Coder	System	19 Oct 2020 18:38:52
Coding entries removed.	Danyel Johnson (b) (4)	19 Oct 2020 18:38:32
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE, PRODUCTSYNONYM: HYDROMET [HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 18:34:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	27 Aug 2020 18:34:38
Data point term sent to Coder	System	24 Aug 2020 17:12:39
User closed query '	System	24 Aug 2020 17:12:26
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' (Site from System).		
Query '	(b) (4), (b) (6)	24 Aug 2020 17:12:26
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' answered with 'data updated' (Site from System).		
User entered 'HYDROMET [hydrocodone/homatropine]' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Aug 2020 17:12:13
User opened query '	Coder Import (b) (4)	14 Aug 2020 07:59:10
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' (Site from System).		
Data point term sent to Coder	System	06 Aug 2020 11:42:52
Data point term sent to Coder	System	06 Aug 2020 11:38:51

v6.020 DTW (1102)

1763 of 2135

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Hydromet'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:10:51
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:10:57
User entered 'Chronic obstructive pulmonary disease'	Danyel Johnson (b) (4)	19 Oct 2020 18:38:32
reason for change: Data Entry Error	(b) (4)	
User entered 'Chronic cough'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Per CDM re-query: Site response is noted; however, only one component of the drug has been noted. Please update the dose to include both components of HYDROMET 5 MG-1.5 MG/5 ML ORAL SYRUP. Thank you.' answered with 'The subject takes a total of 15ml and the dosages are listed in the medication field. Please advise what you want captured in the dose per administration field currently 15ml is listed which is the complete dose given' (Site from DM).	Danyel Johnson (b) (4)	23 Nov 2020 16:19:49
User opened query 'Per CDM re-query: Site response is noted; however, only one component of the drug has been noted. Please update the dose to include both components of HYDROMET 5 MG-1.5 MG/5 ML ORAL SYRUP. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:57:13
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	(b) (4), (b) (6)	20 Nov 2020 16:57:13
' (Site from DM).		
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	Danyel Johnson (b) (4)	13 Nov 2020 13:29:44
' answered with 'Reviewed and updated ' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
User entered '15' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:16:54

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose (1) of this medication as this is not the standard dose for this medication. This is typically in 1.5 MG. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:00:24
	(b) (4), (b) (6)	27 Oct 2020 15:10:58
Query 'Per DM CLR: Please review the dose (1) of this medication as this is not the standard dose for this medication. This is typically in 1.5 MG. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Danyel Johnson (b) (4)	19 Oct 2020 18:36:17
User entered '1.5' reason for change: Data Entry Error	Danyel Johnson (b) (4)	19 Oct 2020 18:36:06
User opened query 'Per DM CLR: Please review the dose (1) of this medication as this is not the standard dose for this medication. This is typically in 1.5 MG. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:00:37
User entered '5/1'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
	(b) (4)	
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:00:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:12
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	19 Oct 2020 18:36:24
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	19 Oct 2020 18:36:06
	(b) (4)	
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:03:15
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 11:41:56
User entered 'ug (ug)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:41:56
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:19
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:21
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 11:41:56
User entered 'as needed (PRN)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:41:56
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 11:41:56
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:41:56
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:12:02
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	06 Aug 2020 11:41:56
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Aug 2020 11:41:56
User entered 'un UNK 2010' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:41:56
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	
	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 11:41:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:41:56
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 11:41:56
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:41:56
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 10:27:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 10:27:42
Data point term sent to Coder	System	18 Sep 2020 15:34:04
Coding entries removed.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Sep 2020 15:33:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:44:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:44:09
Data point term sent to Coder	System	06 Aug 2020 11:44:54
User entered 'Percocet'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Per CDM: Indication is recorded as "Chest/Lung". Please update the indication of this medication to also include the medical condition/diagnosis for the given organs.' (Site from DM). Query 'Per CDM: Indication is recorded as "Chest/Lung". Please update the indication of this medication to also include the medical condition/diagnosis for the given organs.' answered with 'Updated per review of source ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 16:45:55
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	21 Sep 2020 11:49:25
User opened query 'Per CDM: Indication is recorded as "Chest/Lung". Please update the indication of this medication to also include the medical condition/diagnosis for the given organs.' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	18 Sep 2020 15:33:10
User entered 'Chest/Lung'	(b) (4), (b) (6)	02 Sep 2020 12:16:04
	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '7.5/325'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:12:09
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	06 Aug 2020 11:44:13
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 21:08:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 21:08:18
Data point term sent to Coder	System	06 Aug 2020 11:46:55
User entered 'Tizanidine'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Muscle spasms in the lower back'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '4'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'four times daily (QID)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:12:28
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	06 Aug 2020 11:46:08
User entered 'un UNK 2013'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:44:22
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 Oct 2020 18:44:22
Data point term sent to Coder	System	19 Oct 2020 18:43:04
User entered 'Tylenol'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:53:14
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE line #1 matched the time frame noted' (Site from DM).	Danyel Johnson (b) (4)	13 Nov 2020 13:31:36
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hypertensive emergency'	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '650'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	24 Nov 2020 10:48:07
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
Data point term sent to Coder	System	19 Oct 2020 18:55:37
Data point term sent to Coder	System	19 Oct 2020 18:44:11
User entered 'Maalox Plus'	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	19 Oct 2020 18:55:32
User entered 'No (N)'	(b) (4)	
	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Reflux Prophylaxis' reason for change:	Danyel Johnson (b) (4)	19 Oct 2020 18:55:32
Data Entry Error	(b) (4)	
User entered 'Hypertensive Emergency'	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '1'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Other (OTHER)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Dose'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: ADMELOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:33:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:33:29
Data point term sent to Coder	System	19 Oct 2020 19:04:50
Data point term sent to Coder	System	19 Oct 2020 18:45:12
User entered 'Admelog'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hyperglycemia' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:04:41
User entered 'Hypertensive Emergency'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '1-10'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'IU (IU)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'once (ONCE)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Subcutaneous (SUBCUTANEOUS)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:13:27
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 Oct 2020 22:13:27
Data point term sent to Coder	System	19 Oct 2020 18:46:15
User entered 'Ativan'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hypertensive Emergency'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0.5'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Intravenous (INTRAVENOUS)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:16:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:16:36
Data point term sent to Coder	System	19 Oct 2020 18:47:16
User entered 'Melatonin'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hypertensive Emergency'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '3'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:15:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:15:31
Data point term sent to Coder	System	19 Oct 2020 18:48:18
User entered 'Morphine Sulfate'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Abdominal Pain'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '2'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Intravenous (INTRAVENOUS)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: NICARDIPINE HYDROCHLORIDE, PRODUCTSYNONYM: CARDENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:50:34
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 Oct 2020 18:50:34
Data point term sent to Coder	System	19 Oct 2020 18:49:26
User entered 'Cardene'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hypertensive Emergency'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '25'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'other (OTHER)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '5-15mg/hr'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Intravenous (INTRAVENOUS)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:49:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:49:37
Data point term sent to Coder	System	19 Oct 2020 18:50:29
User entered 'Zofran'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Nausea Prophylaxis'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '4'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'once (ONCE)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Intravenous (INTRAVENOUS)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:08:32
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 Oct 2020 05:08:32
Data point term sent to Coder	System	19 Oct 2020 18:51:31
User entered 'Percocet'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Abdominal Pain'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '7.5/325'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:38:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:38:51
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
Data point term sent to Coder	System	19 Oct 2020 18:53:33
User entered 'Protonix'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Acid Reflux Prophylaxis'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '40'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: GLYCOLAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 22:03:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 22:03:47
Data point term sent to Coder	System	19 Oct 2020 18:54:36
User entered 'Glycolox'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'constipation Prophylaxis'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '17'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'g (g)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'once (ONCE)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:21:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:21:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:23:57
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:36:30

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:21:29

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:05:56
Query 'per source, also had abdominal x-ray. please confirm and update.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:05:18
User opened query 'per source, also had abdominal x-ray. please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:40:46
User entered '31 Aug 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:37:51

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:21:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:00
Query 'per source, also had abdominal x-ray. please confirm and update' canceled (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:05:51
User opened query 'per source, also had abdominal x-ray. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:05:33
User entered 'Echocardiogram'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:37:51

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:05:59
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:37:51

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:21:29

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:03
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:37:51

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:21:29

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:09
User entered '31 Aug 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:38:45

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:21:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:10
User entered 'CT scan of pelvis and abdomen'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:38:45

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:12
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:38:45

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:21:29

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:13
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:38:45

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:21:29

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:24
User entered '31 Aug 2020'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:39:17

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:21:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:22
User entered 'CT Scan of head'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:39:17

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:21:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:21
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:39:17

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:21:29

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:19
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:39:17

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'USA-US100-2020-MRNA-1273-P301000003'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'USA-US100-2020-MRNA-1273-P301000003'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:21:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
User entered '20/Sep/2020 13:49'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:21:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered '1'	(b) (4), (b) (6)	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'USA-US100-2020-MRNA-1273-P301000003'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:21:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
User entered '15/Oct/2020 08:16'	System	15 Oct 2020 12:16:49

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:21:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:54:46
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 12:16:49

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'USA-US100-2020-MRNA-1273-P301000003'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:21:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
User entered '16/Oct/2020 12:54'	System	16 Oct 2020 12:54:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:21:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 14:56:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 12:54:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'USA-US100-2020-MRNA-1273-P301000003'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:21:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:10
User entered '03/Nov/2020 14:56'	System	03 Nov 2020 14:56:43

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:21:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 17:06:49
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 14:56:43

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'USA-US100-2020-MRNA-1273-P301000003'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:21:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:21:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:22
User entered '12/Nov/2020 17:08'	System	12 Nov 2020 17:08:35

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:21:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:23
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 17:08:35