

US3692016 (Prod: University of North Carolina at Chapel Hill)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:11:21

All time stamps listed in this document are displayed in GMT

US3692016

Form: Participant Creation

Generated On: 26 Nov 2020 11:11:21

Participant ID

US3692016

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

US3692016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:21

Date of Informed Consent (<i>dd MMM yyyy</i>)	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:11:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:11:21

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:21

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:11:21

Condition	ENVIRONMENTAL ALLERGIES (DOG HAIR, RAGWEED)
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:11:21

Condition	ILIAC ARTERY ANEURYSM
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:11:21

Condition	SLOW PROGRESSION OF ATHEROSCLEROSIS
Start date (dd MMM yyyy)	UN JUN 2019
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)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:11:21

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:11:21

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	29 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:05 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 10:05
Height (<i>xxx.x</i>)	185 cm
Weight (<i>xxx.x</i>)	114.9 kg
BMI (<i>xxx.x</i>)	33.57195 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

EXPOSURE TO LAB PERSONNEL
DAILY, 30-60 MINUTES PER
DAY SPENT IN THE LAB

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:21

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

What was the participant's randomization number? 109456

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:21

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 10:05
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	12:14 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 12:14
Temperature (xxx.x)	36.4 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3692016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	29 AUG 2020
What was the treatment time? (00:00-23:59)	11:44 (24 HR)
Treatment Date and Time (derived)	29 AUG 2020 11:44
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

29 AUG 2020

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

10:57 (24 HR)

Collection date and time (derived)

29 AUG 2020 10:57

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:11:21

Collection date (<i>dd MMM yyyy</i>)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:02	29 AUG 2020 11:02
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:17

PC Open Date & Time

29 AUG 2020 12:04

PC Close Date & Time

29 AUG 2020 14:34

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °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

30 AUG 2020 09:05

PC Open Date & Time

29 AUG 2020 15:29

PC Close Date & Time

30 AUG 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

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

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 06:03

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 05:24

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

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

96.2 °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

02 SEP 2020 05:45

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 21:20

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

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

95.9 °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

04 SEP 2020 07:51

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 09:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:18

PC Open Date & Time

29 AUG 2020 12:04

PC Close Date & Time

29 AUG 2020 14:34

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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

30 AUG 2020 09:05

PC Open Date & Time

29 AUG 2020 15:29

PC Close Date & Time

30 AUG 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

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

31 AUG 2020 06:03

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

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

01 SEP 2020 05:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

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

02 SEP 2020 05:46

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 21:21

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

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

04 SEP 2020 07:51

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 09:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 12:18
PC Open Date & Time	29 AUG 2020 12:04
PC Close Date & Time	29 AUG 2020 14:34

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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

No ☒

Yes ☐

PC Time stamp	30 AUG 2020 09:06
PC Open Date & Time	29 AUG 2020 15:29
PC Close Date & Time	30 AUG 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

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 ☒

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

Yes ☐	
PC Time stamp	31 AUG 2020 06:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

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 ☒

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

Yes ☐	
PC Time stamp	01 SEP 2020 05:25
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

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 ☒

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

Yes ☐	
PC Time stamp	02 SEP 2020 05:46
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

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 ☒

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

Yes ☐	
PC Time stamp	02 SEP 2020 21:21
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

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 ☒

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

Yes ☐	
PC Time stamp	04 SEP 2020 07:52
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

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 ☒

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

Yes ☐	
PC Time stamp	05 SEP 2020 09:53
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3692016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

Was Contact Attempted?

Yes ☒

No ☐

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

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3692016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

Was Contact Attempted?

Yes ☒

No ☐

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

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3692016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

CONCOMITANT MEDICATION
LIST AND ADVERSE EVENT
LIST UPDATED.

If Contact Not Made, please provide Comments

US3692016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	08:18 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 08:18
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:38
Temperature (xxx.x)	36.4 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3692016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

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.

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 23 SEP 2020

What was the treatment time? (00:00-23:59) 10:08 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 10:08

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

US3692016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	23 SEP 2020
Collection time (<i>00:00-23:59</i>)	09:11 (24 HR)
Collection date and time (derived)	23 SEP 2020 09:11

US3692016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:11:21

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:18	23 SEP 2020 09:18
Nasopharyngeal Swab 2	No		

US3692016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 10:40

PC Open Date & Time

23 SEP 2020 10:28

PC Close Date & Time

23 SEP 2020 12:58

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	23 SEP 2020 19:37
PC Open Date & Time	23 SEP 2020 13:53
PC Close Date & Time	24 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 04:58

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 20:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 16:40

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 19:56

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

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 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 07:26

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 10:40

PC Open Date & Time

23 SEP 2020 10:28

PC Close Date & Time

23 SEP 2020 12:58

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 19:37

PC Open Date & Time

23 SEP 2020 13:53

PC Close Date & Time

24 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

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

25 SEP 2020 04:58

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

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

25 SEP 2020 20:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 16:40

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

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

27 SEP 2020 19:56

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

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

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

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

30 SEP 2020 07:26

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 10:41
PC Open Date & Time	23 SEP 2020 10:28
PC Close Date & Time	23 SEP 2020 12:58

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 19:38
PC Open Date & Time	23 SEP 2020 13:53
PC Close Date & Time	24 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

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 ☒

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

Yes ☐	
PC Time stamp	25 SEP 2020 04:58
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

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 ☒

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

Yes ☐	
PC Time stamp	25 SEP 2020 20:05
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

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 ☒

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

Yes ☐	
PC Time stamp	26 SEP 2020 16:40
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

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 ☒

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

Yes ☐	
PC Time stamp	27 SEP 2020 19:57
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

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 ☒

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

Yes ☐	
PC Time stamp	30 SEP 2020 07:27
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3692016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PARTICIPANT REPORTS NO
HEALTH CHANGES. PLANS TO
GET FLU VACCINE ON 10/15/20.

US3692016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

PARTICIPANT REPORTS NO
CHANGES SINCE LAST
CONTACT BY STUDY.

If Contact Not Made, please provide Comments

US3692016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

ROSUVASTATIN CHANGED
FROM QOD TO TWICE WEEKLY

If Contact Not Made, please provide Comments

US3692016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	23 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	8:03 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 8:03
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3692016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

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.

US3692016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	23 OCT 2020
Collection time (<i>00:00-23:59</i>)	8:36 (24 HR)
Collection date and time (derived)	23 OCT 2020 8:36

US3692016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	12 NOV 2020 08:22:58
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

18 DEC 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

25 DEC 2020 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JAN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

19 FEB 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

26 FEB 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 APR 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

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08 JUL 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

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15 JUL 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

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05 AUG 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

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19 AUG 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

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02 SEP 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3692016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3692016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3692016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3692016

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:11:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3692016

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:11:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	29 AUG 2020
Start time (00:00-23:59)	12:14 (24 HR)
AE start date and time (derived)	29 AUG 2020 12:14
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	23 SEP 2020
End time (00:00-23:59)	08:18 (24 HR)
AE End Date and Time (derived)	23 SEP 2020 08:18
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)

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US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

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

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US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

AEID	USA-US123-2020-MRNA-1273-P30 1000001
Adverse event	ILIAC ARTERY ANEURYSM
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)	01 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	02 NOV 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)	01 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	08 NOV 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	4

v6.020 DTW (1102)

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US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

ADMITTED FOR ELECTIVE
OPEN REPAIR OF 3.7CM RIGHT
ILIAC ANEURYSM, WHICH WAS
AN INCIDENTAL FINDING IN
2017. REPAIR WENT WELL AND
STAYED IN HOSPITAL
POST-SURGERY FOR PAIN
MANAGEMENT. DISCHARGED
WITHOUT COMPLICATIONS ON
08-NOVEMBER-2020.
CONSISTENT WITH SAE
REPORTING CRITERIA AS
OUTLINED ON PAGE 74 OF
PROTOCOL AMENDMENT 4,
DUE TO INPATIENT
HOSPITALIZATION.

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:11:21

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

Yes ☒

No ☐

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

	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 2017
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	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

	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 2017	
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	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	ROSUVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	SLOW PROGRESSION OF ATHEROSCLEROSIS
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 ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

	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 JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	12 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

Name of Medication (BUDESONIDE) PULMICORT
INHALER

Prophylaxis Yes ☐
No ☒

Indication REACTIVE AIRWAY DISEASE

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 ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

Name of Medication GLUCOSAMINE - CHONDROITIN
CAPSULE

Prophylaxis Yes ☐
No ☒

Indication JOINT HEALTH

Dose per administration 1500/200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	GARLIC
Prophylaxis	Yes ☐ No ☒
Indication	HEART HEALTH
Dose per administration	UNKNOWN
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 ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

	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	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	TUMERIC CAPSULE
Prophylaxis	Yes ☐ No ☒
Indication	JOINT HEALTH
Dose per administration	1350
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 ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	HEART HEALTH
Dose per administration	81
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 ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

	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 2017
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	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

	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	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	FISH OIL CAPSULES
Prophylaxis	Yes ☐ No ☒
Indication	HEALTH PROMOTION
Dose per administration	1400
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 ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

	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	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	CITRACAL (CALCIUM AND VITAMIN D3)
Prophylaxis	Yes ☐ No ☒
Indication	BONE HEALTH
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	COENZYME Q10
Prophylaxis	Yes ☐ No ☒
Indication	HEART HEALTH
Dose per administration	400
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 ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

	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)	2	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

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)	21 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	ROSUVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERLIPIDEMIA
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	2X A WEEK Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

	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)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	PAIN (POST-BILATERAL ILIAC ANEURYSM REPAIR)
Dose per administration	325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	2 TABLETS Q6N Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

	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)		08 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

	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)	08 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	DILAUDID
Prophylaxis	Yes ☐ No ☒
Indication	PAIN (POST BILATERAL ILIAC ANEURYSM REPAIR)
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	
1 TABLET PRN/Q4 HOURS FOR UP TO 5 DAYS	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

	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)	08 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	SENOKOT
Prophylaxis	Yes ☐ No ☒
Indication	STIMULANT LAXATIVE
Dose per administration	17.2
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 ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

	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)		08 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	CIALIS
Prophylaxis	Yes ☐ No ☒
Indication	ERECTILE DYSFUNCTION
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	1-2 TABLETS PRN Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	PREVIDENT 1.1%
Prophylaxis	Yes ☒ No ☐
Indication	ORAL HYGIENE
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	ADMINISTRATION
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 ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	PREVENTIL
Prophylaxis	Yes ☐ No ☒
Indication	WHEEZING
Dose per administration	180
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	PRN Q6 HOURS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

Name of Medication	CLINDAMYCIN 1%
Prophylaxis	Yes ☐ No ☒
Indication	FOLLICULITIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	APPLICATION
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 ☐

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

	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 2005
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	☒

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:11:21

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:11:21

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
02 NOV 2020	OPEN ILIAC ARTERY REPAIR	Medical History	

US3692016

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:11:21

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

US3692016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:11:21

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 ☐

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

SAEID	USA-US123-2020-MRNA-1273-P301000001
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	CYNTHIA
Investigator's Last Name	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:11:21

SAEID	USA-US123-2020-MRNA-1273-P301000001
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	CYNTHIA
Investigator's Last Name	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/NOV/2020 20:37
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

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:11:21

SAEID	USA-US123-2020-MRNA-1273-P301000001
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	CYNTHIA
Investigator's Last Name	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/NOV/2020 19:30
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

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:11:21

SAEID	USA-US123-2020-MRNA-1273-P301000001
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	CYNTHIA
Investigator's Last Name	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	17/NOV/2020 13:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:11:21

SAEID	USA-US123-2020-MRNA-1273-P301000001
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	CYNTHIA
Investigator's Last Name	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	18/NOV/2020 18:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3692016 (Prod: University of North Carolina at Chapel Hill)

US3692016

Form: Participant Creation

Generated On: 26 Nov 2020 11:11:21

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3692016'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Aug 2020 16:19:31

US3692016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:49:51

US3692016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 16:19:32

US3692016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:49:51

US3692016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	29 Aug 2020 14:49:51

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 16:19:33

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[Age](#)

Audit	User	Time (GMT)
User entered '55'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '55'	System	29 Aug 2020 14:50:22

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

White

Audit	User	Time (GMT)
User entered '0'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[Black](#)

Audit	User	Time (GMT)
User entered '1'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

Unknown

Audit	User	Time (GMT)
User entered '0'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:11:21

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:51:24

US3692016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:50:22

US3692016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	29 Aug 2020 14:50:22

US3692016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '2020'	System	29 Aug 2020 14:50:22

US3692016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:21

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:50:22

US3692016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:50:22

US3692016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:50:22

US3692016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:50:22

US3692016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:50:22

US3692016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 16:19:32

US3692016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:11:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 14:50:59

US3692016

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:50:59

US3692016

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:11:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:33
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 17:42:24
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:21

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Bronchial hyperreactivity, LLT: Reactive airways disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:44:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:44:57
Data point term sent to Coder	System	01 Sep 2020 17:43:49
User entered 'reactive airway disease'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:43:16

US3692016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'un UNK 2000'	Abigail Riddick (b) (4)	01 Sep 2020 17:43:16
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 17:43:16
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 17:43:16
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 17:43:16
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 17:43:16
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	01 Sep 2020 17:43:16

US3692016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '2000'	System	01 Sep 2020 17:43:16

US3692016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:43:16

US3692016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:43:16

US3692016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:11:21

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 07:13:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 07:13:32
Data point term sent to Coder	System	01 Sep 2020 17:44:55
User entered 'environmental allergies (dog hair, ragweed)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:44:03

US3692016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'un UNK 2017'	Abigail Riddick (b) (4)	01 Sep 2020 17:44:03
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 17:44:03
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:11:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 17:44:03
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 17:44:03
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:11:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 17:44:03
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	01 Sep 2020 17:44:03

US3692016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '2017'	System	01 Sep 2020 17:44:03

US3692016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:44:03

US3692016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:44:03

US3692016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:11:21

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User coded data point as SOC: Vascular disorders, HLG: Aneurysms and artery dissections, HLT: Peripheral aneurysms and dissections, PT: Peripheral artery aneurysm, LLT: Iliac artery aneurysm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:46:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:46:47
Data point term sent to Coder	System	01 Sep 2020 17:45:59
User entered 'iliac artery aneurysm'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:45:47

US3692016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'un UNK 2016'	Abigail Riddick (b) (4)	01 Sep 2020 17:45:47
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 17:45:47
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:11:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 17:45:47
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 17:45:47
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:11:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 17:45:47
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	01 Sep 2020 17:45:47

US3692016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '2016'	System	01 Sep 2020 17:45:47

US3692016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:45:47

US3692016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:45:47

US3692016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:11:21

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Arteriosclerosis, LLT: Atherosclerosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:22:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:22:31
Data point term sent to Coder	System	23 Oct 2020 23:14:18
User entered 'slow progression of athersclerosis'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:14:12

US3692016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'un Jun 2019'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:14:12

US3692016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:14:12

US3692016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:11:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:14:12

US3692016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:14:12

US3692016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:11:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:53
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:14:12

US3692016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	23 Oct 2020 23:14:12

US3692016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '2019'	System	23 Oct 2020 23:14:12

US3692016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 23:14:12

US3692016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 23:14:12

US3692016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:11:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 17:04:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 17:04:53
Data point term sent to Coder	System	17 Nov 2020 16:48:51
User entered 'Erectile Dysfunction'	Maria Stetson (b) (4)	17 Nov 2020 16:48:45
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	Maria Stetson (b) (4) (b) (4)	17 Nov 2020 16:48:45

US3692016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Maria Stetson (b) (4) (b) (4)	17 Nov 2020 16:48:45

US3692016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:11:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	17 Nov 2020 16:48:45

US3692016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	Maria Stetson (b) (4) (b) (4)	17 Nov 2020 16:48:45

US3692016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:11:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Maria Stetson (b) (4) (b) (4)	17 Nov 2020 16:48:45

US3692016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 16:48:45

US3692016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 16:48:45

US3692016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 16:48:45

US3692016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 16:48:45

US3692016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:11:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Folliculitis, LLT: Folliculitis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:22:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:22:49
Data point term sent to Coder	System	17 Nov 2020 20:21:59
User entered 'Folliculitis'	Maria Stetson (b) (4)	17 Nov 2020 20:21:39
	(b) (4)	

US3692016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Maria Stetson (b) (4) (b) (4)	17 Nov 2020 20:21:39

US3692016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Maria Stetson (b) (4) (b) (4)	17 Nov 2020 20:21:39

US3692016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:11:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	17 Nov 2020 20:21:39

US3692016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	Maria Stetson (b) (4) (b) (4)	17 Nov 2020 20:21:39

US3692016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:11:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Maria Stetson (b) (4) (b) (4)	17 Nov 2020 20:21:39

US3692016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	17 Nov 2020 20:21:39

US3692016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '2005'	System	17 Nov 2020 20:21:39

US3692016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:21:39

US3692016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:21:39

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 18:33:49
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered with 'Date is correct. Several screening assessments were completed on the day of entry.' (Site from System).	Mandy Tipton (b) (4)	01 Sep 2020 22:19:56
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 17:50:56
User entered '29 Aug 2020'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '10:05'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '29 Aug 2020 10:05'	System	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '185' cm	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56
DataPoint set to visible.	(b) (4) System	29 Aug 2020 14:50:59

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '114.9' kg	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56
DataPoint set to visible.	(b) (4) System	29 Aug 2020 14:50:59

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '33.57195'	System	01 Sep 2020 17:50:56
DataPoint set to visible.	System	29 Aug 2020 14:50:59

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	01 Sep 2020 17:50:56
DataPoint set to visible.	System	29 Aug 2020 14:50:59

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 09:01:35
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'Updated.' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:40:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:40:03
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:34:06
User entered '36.6' C	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Mandy Tipton (b) (4)	09 Sep 2020 21:40:03
User entered 'Oral (Oral)'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4)	09 Sep 2020 21:40:03
User entered '76'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4)	09 Sep 2020 21:40:03
User entered '16'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4)	09 Sep 2020 21:40:03
User entered '148'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4)	09 Sep 2020 21:40:03
User entered '97'	Abigail Riddick (b) (4)	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 17:50:56

US3692016

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Maria Stetson (b) (4)	01 Oct 2020 15:37:36
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 17:51:24

US3692016

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Aug 2020' reason for change: Data Entry Error	Maria Stetson (b) (4)	01 Oct 2020 15:37:36
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 17:51:24

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

[Specify](#)

Audit	User	Time (GMT)
User entered 'exposure to lab personnel daily, 30-60 minutes per day spent in the lab'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '0'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '0'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '0'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '0'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '1'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:11:21

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:04:39

US3692016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:52:56

US3692016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:52:56

US3692016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:52:56

US3692016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	29 Aug 2020 14:52:56

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '29 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 14:45:36

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '109456'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 14:45:36

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 14:45:36

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:53:27

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:53:27

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:53:27

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:21

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:53:27

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:21

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 14:53:27

US3692016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:27:50
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:27:49

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:21

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:51:56
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated.' (Site from DM).	Mandy Tipton (b) (4)	09 Sep 2020 21:40:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 21:40:41
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:33:35
User entered '185' cm	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4)	09 Sep 2020 21:40:41
User entered '114.9' kg	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:21

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:51:56
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated.' (Site from DM).	Mandy Tipton (b) (4)	09 Sep 2020 21:40:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 21:40:41
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:33:35
User entered '185' cm	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4)	09 Sep 2020 21:40:41
User entered '114.9' kg	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '10:05'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '29 Aug 2020 10:05'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '16'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '148'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '97'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:21

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:51:56
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated.' (Site from DM).	Mandy Tipton (b) (4)	09 Sep 2020 21:40:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Sep 2020 21:40:41
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:33:35
User entered '185' cm	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:11:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4)	09 Sep 2020 21:40:41
User entered '114.9' kg	Abigail Riddick (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '12:14'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:14'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '16'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '141'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '99'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 18:10:57

US3692016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:12:42

US3692016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:12:42

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '11:44'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:44'	System	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Mandy Tipton (b) (4) (b) (4)	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 15:50:09

US3692016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	02 Sep 2020 12:17:37

US3692016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Mandy Tipton (b) (4) (b) (4)	02 Sep 2020 12:17:37

US3692016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:57'	Mandy Tipton (b) (4) (b) (4)	02 Sep 2020 12:17:37

US3692016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '29 Aug 2020 10:57'	System	02 Sep 2020 12:17:37

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:11:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	02 Sep 2020 12:17:48
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	02 Sep 2020 12:17:48
User entered '29 Aug 2020' reason for change: Data Entry Error	Mandy Tipton (b) (4)	02 Sep 2020 12:17:48
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	02 Sep 2020 12:17:17
User entered empty.	Mandy Tipton (b) (4)	02 Sep 2020 12:17:17

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mandy Tipton (b) (4) (b) (4)	02 Sep 2020 12:17:17

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	02 Sep 2020 12:17:17

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:02'	Mandy Tipton (b) (4) (b) (4)	02 Sep 2020 12:17:17

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:02'	System	02 Sep 2020 12:17:48
User entered empty.	System	02 Sep 2020 12:17:17

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mandy Tipton (b) (4) (b) (4)	02 Sep 2020 12:17:17

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:17:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 12:17:52
User entered 'No (N)' reason for change: Data Entry Error	Mandy Tipton (b) (4)	02 Sep 2020 12:17:52
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 12:17:17
User entered empty.	Mandy Tipton (b) (4)	02 Sep 2020 12:17:17

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	02 Sep 2020 12:17:17

US3692016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 12:17:17

US3692016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	02 Sep 2020 12:16:44

US3692016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 12:16:44

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:16:53', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a4c3e617-d5bb-46a8-9788-66a1d3847a28'	System	29 Aug 2020 16:17:50
User entered 'Yes (Y)'	System	29 Aug 2020 16:17:50

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:17:37', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a4c3e617-d5bb-46a8-9788-66a1d3847a28'	System	29 Aug 2020 16:17:50
User entered '97.5'	System	29 Aug 2020 16:17:50

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:17:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a4c3e617-d5bb-46a8-9788-66a1d3847a28'	System	29 Aug 2020 16:17:50
User entered 'No (N)'	System	29 Aug 2020 16:17:50

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:17:48', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a4c3e617-d5bb-46a8-9788-66a1d3847a28'	System	29 Aug 2020 16:17:50
User entered '29 Aug 2020 12:17'	System	29 Aug 2020 16:17:50

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:04'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 14:34'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:11', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '487b9444-cbfa-42aa-add1-f957184490d2'	System	30 Aug 2020 13:06:35
User entered 'Yes (Y)'	System	30 Aug 2020 13:06:35

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '487b9444-cbfa-42aa-add1-f957184490d2'	System	30 Aug 2020 13:06:35
User entered '96.4'	System	30 Aug 2020 13:06:35

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:22', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '487b9444-cbfa-42aa-add1-f957184490d2'	System	30 Aug 2020 13:06:35
User entered 'No (N)'	System	30 Aug 2020 13:06:35

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:25', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '487b9444-cbfa-42aa-add1-f957184490d2'	System	30 Aug 2020 13:06:35
User entered '30 Aug 2020 09:05'	System	30 Aug 2020 13:06:35

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 15:29'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 2'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:02:53', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0648c69d-e734-4642-a8b3-3eae964ee74c'	System	31 Aug 2020 10:03:09
User entered 'Yes (Y)'	System	31 Aug 2020 10:03:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:02:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0648c69d-e734-4642-a8b3-3eae964ee74c'	System	31 Aug 2020 10:03:09
User entered '96.1'	System	31 Aug 2020 10:03:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0648c69d-e734-4642-a8b3-3eae964ee74c'	System	31 Aug 2020 10:03:09
User entered 'No (N)'	System	31 Aug 2020 10:03:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:08', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0648c69d-e734-4642-a8b3-3eae964ee74c' User entered '31 Aug 2020 06:03'	System	31 Aug 2020 10:03:09
	System	31 Aug 2020 10:03:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 3'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:23:37', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4de471a5-96ef-4ef9-ac45-a8dfcb1dadff'	System	01 Sep 2020 09:24:49
User entered 'Yes (Y)'	System	01 Sep 2020 09:24:49

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:41', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4de471a5-96ef-4ef9-ac45-a8dfcb1dadff'	System	01 Sep 2020 09:24:49
User entered '97.0'	System	01 Sep 2020 09:24:49

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:45', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4de471a5-96ef-4ef9-ac45-a8dfcb1dadff'	System	01 Sep 2020 09:24:49
User entered 'No (N)'	System	01 Sep 2020 09:24:49

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:48', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4de471a5-96ef-4ef9-ac45-a8dfcb1dadff'	System	01 Sep 2020 09:24:49
User entered '01 Sep 2020 05:24'	System	01 Sep 2020 09:24:49

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 4'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a5a95e4a-65e1-409b-ace3-70bd738a4168'	System	02 Sep 2020 09:45:51
User entered 'Yes (Y)'	System	02 Sep 2020 09:45:51

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:42', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a5a95e4a-65e1-409b-ace3-70bd738a4168' User entered '96.2'	System	02 Sep 2020 09:45:51
	System	02 Sep 2020 09:45:51

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a5a95e4a-65e1-409b-ace3-70bd738a4168'	System	02 Sep 2020 09:45:51
User entered 'No (N)'	System	02 Sep 2020 09:45:51

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:48', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a5a95e4a-65e1-409b-ace3-70bd738a4168'	System	02 Sep 2020 09:45:51
User entered '02 Sep 2020 05:45'	System	02 Sep 2020 09:45:51

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 5'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:20:50', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '79499409-2ea8-4f36-b21d-cb7d8db01281'	System	03 Sep 2020 01:21:02
User entered 'Yes (Y)'	System	03 Sep 2020 01:21:02

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:20:54', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '79499409-2ea8-4f36-b21d-cb7d8db01281'	System	03 Sep 2020 01:21:02
User entered '98.1'	System	03 Sep 2020 01:21:02

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:20:57', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '79499409-2ea8-4f36-b21d-cb7d8db01281'	System	03 Sep 2020 01:21:02
User entered 'No (N)'	System	03 Sep 2020 01:21:02

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:20:59', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '79499409-2ea8-4f36-b21d-cb7d8db01281'	System	03 Sep 2020 01:21:02
User entered '02 Sep 2020 21:20'	System	03 Sep 2020 01:21:02

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 6'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3e2ade6a-1be0-457b-8ad9-e3d15fab7abd'	System	04 Sep 2020 11:51:38
User entered 'Yes (Y)'	System	04 Sep 2020 11:51:38

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:32', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3e2ade6a-1be0-457b-8ad9-e3d15fab7abd'	System	04 Sep 2020 11:51:38
User entered '95.9'	System	04 Sep 2020 11:51:38

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3e2ade6a-1be0-457b-8ad9-e3d15fab7abd'	System	04 Sep 2020 11:51:38
User entered 'No (N)'	System	04 Sep 2020 11:51:38

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:37', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3e2ade6a-1be0-457b-8ad9-e3d15fab7abd'	System	04 Sep 2020 11:51:38
User entered '04 Sep 2020 07:51'	System	04 Sep 2020 11:51:38

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 7'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:03', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '37b87cbf-7eeb-48da-8d8e-393f52904e8a'	System	05 Sep 2020 13:53:16
User entered 'Yes (Y)'	System	05 Sep 2020 13:53:16

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:08', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '37b87cbf-7eeb-48da-8d8e-393f52904e8a' User entered '97.0'	System	05 Sep 2020 13:53:16
	System	05 Sep 2020 13:53:16

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '37b87cbf-7eeb-48da-8d8e-393f52904e8a'	System	05 Sep 2020 13:53:16
User entered 'No (N)'	System	05 Sep 2020 13:53:16

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:13', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '37b87cbf-7eeb-48da-8d8e-393f52904e8a'	System	05 Sep 2020 13:53:16
User entered '05 Sep 2020 09:53'	System	05 Sep 2020 13:53:16

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5cb19a35-3d07-496a-b86d-0ab414d74ed6'	System	29 Aug 2020 16:18:20
User entered 'None (1)'	System	29 Aug 2020 16:18:20

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5cb19a35-3d07-496a-b86d-0ab414d74ed6'	System	29 Aug 2020 16:18:20
User entered 'No (N)'	System	29 Aug 2020 16:18:20

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5cb19a35-3d07-496a-b86d-0ab414d74ed6'	System	29 Aug 2020 16:18:20
User entered 'No (N)'	System	29 Aug 2020 16:18:20

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5cb19a35-3d07-496a-b86d-0ab414d74ed6'	System	29 Aug 2020 16:18:20
User entered 'None (1)'	System	29 Aug 2020 16:18:20

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:19', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5cb19a35-3d07-496a-b86d-0ab414d74ed6'	System	29 Aug 2020 16:18:20
User entered '29 Aug 2020 12:18'	System	29 Aug 2020 16:18:20

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:04'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 14:34'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:32', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e6c15bfa-3f3e-480a-b7e7-e2a40571a126'	System	30 Aug 2020 13:06:38
User entered 'None (1)'	System	30 Aug 2020 13:06:38

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e6c15bfa-3f3e-480a-b7e7-e2a40571a126'	System	30 Aug 2020 13:06:38
User entered 'No (N)'	System	30 Aug 2020 13:06:38

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e6c15bfa-3f3e-480a-b7e7-e2a40571a126'	System	30 Aug 2020 13:06:38
User entered 'No (N)'	System	30 Aug 2020 13:06:38

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:42', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e6c15bfa-3f3e-480a-b7e7-e2a40571a126'	System	30 Aug 2020 13:06:38
User entered 'None (1)'	System	30 Aug 2020 13:06:38

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:44', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'e6c15bfa-3f3e-480a-b7e7-e2a40571a126'	System	30 Aug 2020 13:06:38
User entered '30 Aug 2020 09:05'	System	30 Aug 2020 13:06:38

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 15:29'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 2'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:12', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '58d20d2f-f302-444f-a845-a80f72bfb965'	System	31 Aug 2020 10:03:30
User entered 'None (1)'	System	31 Aug 2020 10:03:30

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '58d20d2f-f302-444f-a845-a80f72bfb965'	System	31 Aug 2020 10:03:30
User entered 'No (N)'	System	31 Aug 2020 10:03:30

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:19', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '58d20d2f-f302-444f-a845-a80f72bfb965'	System	31 Aug 2020 10:03:30
User entered 'No (N)'	System	31 Aug 2020 10:03:30

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:22', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '58d20d2f-f302-444f-a845-a80f72bfb965'	System	31 Aug 2020 10:03:30
User entered 'None (1)'	System	31 Aug 2020 10:03:30

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:25', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '58d20d2f-f302-444f-a845-a80f72bfb965'	System	31 Aug 2020 10:03:30
User entered '31 Aug 2020 06:03'	System	31 Aug 2020 10:03:30

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 3'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94b3ff56-8590-447f-9774-521ce10d3d4c'	System	01 Sep 2020 09:25:05
User entered 'None (1)'	System	01 Sep 2020 09:25:05

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:56', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94b3ff56-8590-447f-9774-521ce10d3d4c'	System	01 Sep 2020 09:25:05
User entered 'No (N)'	System	01 Sep 2020 09:25:05

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:24:59', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94b3ff56-8590-447f-9774-521ce10d3d4c'	System	01 Sep 2020 09:25:05
User entered 'No (N)'	System	01 Sep 2020 09:25:05

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94b3ff56-8590-447f-9774-521ce10d3d4c'	System	01 Sep 2020 09:25:05
User entered 'None (1)'	System	01 Sep 2020 09:25:05

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '94b3ff56-8590-447f-9774-521ce10d3d4c'	System	01 Sep 2020 09:25:05
User entered '01 Sep 2020 05:25'	System	01 Sep 2020 09:25:05

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 4'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ea416b7d-3655-48a4-9933-be7447c5f3c1'	System	02 Sep 2020 09:46:04
User entered 'None (1)'	System	02 Sep 2020 09:46:04

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:54', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ea416b7d-3655-48a4-9933-be7447c5f3c1'	System	02 Sep 2020 09:46:04
User entered 'No (N)'	System	02 Sep 2020 09:46:04

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:45:57', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ea416b7d-3655-48a4-9933-be7447c5f3c1'	System	02 Sep 2020 09:46:04
User entered 'No (N)'	System	02 Sep 2020 09:46:04

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ea416b7d-3655-48a4-9933-be7447c5f3c1'	System	02 Sep 2020 09:46:04
User entered 'None (1)'	System	02 Sep 2020 09:46:04

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ea416b7d-3655-48a4-9933-be7447c5f3c1'	System	02 Sep 2020 09:46:04
User entered '02 Sep 2020 05:46'	System	02 Sep 2020 09:46:04

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 5'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b275e14d-dcae-425d-b396-c5c66e9293ed'	System	03 Sep 2020 01:21:14
User entered 'None (1)'	System	03 Sep 2020 01:21:14

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b275e14d-dcae-425d-b396-c5c66e9293ed'	System	03 Sep 2020 01:21:14
User entered 'No (N)'	System	03 Sep 2020 01:21:14

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:06', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b275e14d-dcae-425d-b396-c5c66e9293ed'	System	03 Sep 2020 01:21:14
User entered 'No (N)'	System	03 Sep 2020 01:21:14

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:09', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b275e14d-dcae-425d-b396-c5c66e9293ed' User entered 'None (1)'	System	03 Sep 2020 01:21:14
	System	03 Sep 2020 01:21:14

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b275e14d-dcae-425d-b396-c5c66e9293ed' User entered '02 Sep 2020 21:21'	System	03 Sep 2020 01:21:14
	System	03 Sep 2020 01:21:14

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 6'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:40', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a29e0da8-fa67-4812-81eb-7785d1f0dc9d'	System	04 Sep 2020 11:51:57
User entered 'None (1)'	System	04 Sep 2020 11:51:57

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a29e0da8-fa67-4812-81eb-7785d1f0dc9d'	System	04 Sep 2020 11:51:57
User entered 'No (N)'	System	04 Sep 2020 11:51:57

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:45', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a29e0da8-fa67-4812-81eb-7785d1f0dc9d'	System	04 Sep 2020 11:51:57
User entered 'No (N)'	System	04 Sep 2020 11:51:57

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:50', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a29e0da8-fa67-4812-81eb-7785d1f0dc9d'	System	04 Sep 2020 11:51:57
User entered 'None (1)'	System	04 Sep 2020 11:51:57

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:51:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a29e0da8-fa67-4812-81eb-7785d1f0dc9d'	System	04 Sep 2020 11:51:57
User entered '04 Sep 2020 07:51'	System	04 Sep 2020 11:51:57

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 7'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:18', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '34be6954-cfa7-421e-a5c3-ea89b3fab67f'	System	05 Sep 2020 13:53:32
User entered 'None (1)'	System	05 Sep 2020 13:53:32

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:21', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '34be6954-cfa7-421e-a5c3-ea89b3fab67f'	System	05 Sep 2020 13:53:32
User entered 'No (N)'	System	05 Sep 2020 13:53:32

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '34be6954-cfa7-421e-a5c3-ea89b3fab67f' User entered 'No (N)'	System	05 Sep 2020 13:53:32

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:28', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '34be6954-cfa7-421e-a5c3-ea89b3fab67f'	System	05 Sep 2020 13:53:32
User entered 'None (1)'	System	05 Sep 2020 13:53:32

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:30', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '34be6954-cfa7-421e-a5c3-ea89b3fab67f'	System	05 Sep 2020 13:53:32
User entered '05 Sep 2020 09:53'	System	05 Sep 2020 13:53:32

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered 'None (0)'	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:28', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered 'None (0)'	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:30', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered 'None (0)'	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:36', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered 'None (0)'	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered 'None (0)'	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered 'None (0)'	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:44', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered 'No (N)'	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-29T12:18:47', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '2ffc286c-fafa-452b-963c-fe1c1aed13f0'	System	29 Aug 2020 16:18:49
User entered '29 Aug 2020 12:18'	System	29 Aug 2020 16:18:49

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:04'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 14:34'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:50', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0'	System	30 Aug 2020 13:06:41
User entered 'None (0)'	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:53', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0'	System	30 Aug 2020 13:06:41
User entered 'None (0)'	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:57', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0'	System	30 Aug 2020 13:06:41
User entered 'None (0)'	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:05:59', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0'	System	30 Aug 2020 13:06:41
User entered 'None (0)'	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:06:01', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0'	System	30 Aug 2020 13:06:41
User entered 'None (0)'	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:06:03', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0'	System	30 Aug 2020 13:06:41
User entered 'None (0)'	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:06:11', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0'	System	30 Aug 2020 13:06:41
User entered 'No (N)'	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-30T09:06:12', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d197d87-5d8f-4214-8e63-732cf6227ff0'	System	30 Aug 2020 13:06:41
User entered '30 Aug 2020 09:06'	System	30 Aug 2020 13:06:41

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 15:29'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 2'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:30', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3'	System	31 Aug 2020 10:03:52
User entered 'None (0)'	System	31 Aug 2020 10:03:52

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:32', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3'	System	31 Aug 2020 10:03:52
User entered 'None (0)'	System	31 Aug 2020 10:03:52

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3'	System	31 Aug 2020 10:03:52
User entered 'None (0)'	System	31 Aug 2020 10:03:52

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:37', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3'	System	31 Aug 2020 10:03:52
User entered 'None (0)'	System	31 Aug 2020 10:03:52

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3'	System	31 Aug 2020 10:03:52
User entered 'None (0)'	System	31 Aug 2020 10:03:52

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:41', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3'	System	31 Aug 2020 10:03:52
User entered 'None (0)'	System	31 Aug 2020 10:03:52

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:44', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3'	System	31 Aug 2020 10:03:52
User entered 'No (N)'	System	31 Aug 2020 10:03:52

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-08-31T06:03:48', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1e1a334-9653-4d8b-b60e-631b94bac2d3'	System	31 Aug 2020 10:03:52
User entered '31 Aug 2020 06:03'	System	31 Aug 2020 10:03:52

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 3'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:08', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered 'None (0)'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered 'None (0)'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:13', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf'	System	01 Sep 2020 09:25:24
User entered 'None (0)'	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:15', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered 'None (0)'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf'	System	01 Sep 2020 09:25:24
User entered 'None (0)'	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:18', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered 'None (0)'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:21', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf'	System	01 Sep 2020 09:25:24
User entered 'No (N)'	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-01T05:25:23', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '1d85e673-3547-4ca7-bd84-93988a87bbdf' User entered '01 Sep 2020 05:25'	System	01 Sep 2020 09:25:24
	System	01 Sep 2020 09:25:24

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 4'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:12', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21'	System	02 Sep 2020 09:46:34
User entered 'None (0)'	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:14', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21'	System	02 Sep 2020 09:46:34
User entered 'None (0)'	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21'	System	02 Sep 2020 09:46:34
User entered 'None (0)'	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:19', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21'	System	02 Sep 2020 09:46:34
User entered 'None (0)'	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:22', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21'	System	02 Sep 2020 09:46:34
User entered 'None (0)'	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:24', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21'	System	02 Sep 2020 09:46:34
User entered 'None (0)'	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:28', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21'	System	02 Sep 2020 09:46:34
User entered 'No (N)'	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T05:46:30', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '3fae7376-dc03-4be5-b5c1-7ae4c92a2b21'	System	02 Sep 2020 09:46:34
User entered '02 Sep 2020 05:46'	System	02 Sep 2020 09:46:34

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 5'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:13', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a'	System	03 Sep 2020 01:21:32
User entered 'None (0)'	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:15', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a'	System	03 Sep 2020 01:21:32
User entered 'None (0)'	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:17', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a'	System	03 Sep 2020 01:21:32
User entered 'None (0)'	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:19', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a' User entered 'None (0)'	System	03 Sep 2020 01:21:32
	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:20', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a'	System	03 Sep 2020 01:21:32
User entered 'None (0)'	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:22', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a'	System	03 Sep 2020 01:21:32
User entered 'None (0)'	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:27', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a'	System	03 Sep 2020 01:21:32
User entered 'No (N)'	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-02T21:21:29', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '6a88d921-cd24-4545-97f5-aa1b7ca0651a'	System	03 Sep 2020 01:21:32
User entered '02 Sep 2020 21:21'	System	03 Sep 2020 01:21:32

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 6'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8'	System	04 Sep 2020 11:52:21
User entered 'None (0)'	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered 'None (0)'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:06', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8'	System	04 Sep 2020 11:52:21
User entered 'None (0)'	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:07', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8'	System	04 Sep 2020 11:52:21
User entered 'None (0)'	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:09', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered 'None (0)'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:11', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered 'None (0)'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8'	System	04 Sep 2020 11:52:21
User entered 'No (N)'	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-04T07:52:18', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'f32ade0f-851d-4199-a74d-0923e1a41ad8' User entered '04 Sep 2020 07:52'	System	04 Sep 2020 11:52:21
	System	04 Sep 2020 11:52:21

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 7'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:33', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3'	System	05 Sep 2020 13:53:53
User entered 'None (0)'	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3'	System	05 Sep 2020 13:53:53
User entered 'None (0)'	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3'	System	05 Sep 2020 13:53:53
User entered 'None (0)'	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3'	System	05 Sep 2020 13:53:53
User entered 'None (0)'	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:41', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3'	System	05 Sep 2020 13:53:53
User entered 'None (0)'	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3'	System	05 Sep 2020 13:53:53
User entered 'None (0)'	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:47', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3'	System	05 Sep 2020 13:53:53
User entered 'No (N)'	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-05T09:53:49', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'edeccb7c-be8d-4b5e-80c3-d22d359b2ac3' User entered '05 Sep 2020 09:53'	System	05 Sep 2020 13:53:53
	System	05 Sep 2020 13:53:53

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:50:09

US3692016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 20:28:07

US3692016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '07 Sep 2020'	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 20:28:07

US3692016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 20:28:07

US3692016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 20:28:07

US3692016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 20:28:14

US3692016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:28:14

US3692016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	14 Sep 2020 23:29:48

US3692016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Kristi Kirkland (b) (4) (b) (4)	14 Sep 2020 23:29:48

US3692016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kristi Kirkland (b) (4) (b) (4)	14 Sep 2020 23:29:48

US3692016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	14 Sep 2020 23:29:48

US3692016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	14 Sep 2020 23:29:52

US3692016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 23:29:52

US3692016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexander Bradley (b) (4)	21 Sep 2020 18:25:23
	(b) (4)	

US3692016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Alexander Bradley (b) (4)	21 Sep 2020 18:25:23
	(b) (4)	

US3692016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexander Bradley (b) (4)	21 Sep 2020 18:25:23

US3692016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Concomitant medication list and adverse event list updated.' reason for change: Data Entry Error	Maria Stetson (b) (4)	01 Oct 2020 18:13:20
User entered empty.	Alexander Bradley (b) (4)	21 Sep 2020 18:25:23

US3692016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexander Bradley (b) (4)	21 Sep 2020 18:25:27
	(b) (4)	

US3692016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:25:27

US3692016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:27:02

US3692016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:27:02

US3692016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:27:02

US3692016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	23 Sep 2020 14:27:02

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '08:18'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 08:18'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '18'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '120'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:11:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '10:38'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 10:38'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '20'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '131'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '85'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:11:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 14:59:01

US3692016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Mandy Tipton (b) (4)	23 Sep 2020 14:54:33
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	23 Sep 2020 14:27:14

US3692016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Mandy Tipton (b) (4)	23 Sep 2020 14:54:33
User entered '23 Sep 2020'	Mandy Tipton (b) (4)	23 Sep 2020 14:27:14

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '10:08'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 10:08'	System	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 14:25:34

US3692016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:56:10

US3692016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:56:10

US3692016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '09:11'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:56:10

US3692016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:11'	System	23 Sep 2020 14:56:10

US3692016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:11:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:57:05

US3692016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:57:05

US3692016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:57:05

US3692016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:18'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:57:05

US3692016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:18'	System	23 Sep 2020 14:57:05

US3692016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:57:05

US3692016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:57:05

US3692016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:57:05

US3692016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 14:57:05

US3692016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:26:46

US3692016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:26:46

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:39:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b7a67884-f709-4708-88a0-a1db81252d7b'	System	23 Sep 2020 14:40:03
User entered 'Yes (Y)'	System	23 Sep 2020 14:40:03

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:39:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b7a67884-f709-4708-88a0-a1db81252d7b'	System	23 Sep 2020 14:40:03
User entered '97.5'	System	23 Sep 2020 14:40:03

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:39:55', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b7a67884-f709-4708-88a0-a1db81252d7b'	System	23 Sep 2020 14:40:03
User entered 'No (N)'	System	23 Sep 2020 14:40:03

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'b7a67884-f709-4708-88a0-a1db81252d7b'	System	23 Sep 2020 14:40:03
User entered '23 Sep 2020 10:40'	System	23 Sep 2020 14:40:03

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 10:28'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:58'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '42c5bc33-1fb1-452c-a149-a0d086beb65f' User entered 'Yes (Y)'	System	23 Sep 2020 23:37:42
	System	23 Sep 2020 23:37:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:32', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '42c5bc33-1fb1-452c-a149-a0d086beb65f' User entered '97.9'	System	23 Sep 2020 23:37:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:36', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '42c5bc33-1fb1-452c-a149-a0d086beb65f'	System	23 Sep 2020 23:37:42
User entered 'No (N)'	System	23 Sep 2020 23:37:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '42c5bc33-1fb1-452c-a149-a0d086beb65f' User entered '23 Sep 2020 19:37'	System	23 Sep 2020 23:37:42
	System	23 Sep 2020 23:37:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 13:53'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 2'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '281c5c51-0ead-43d4-ae64-9844cec5a4d4'	System	25 Sep 2020 08:58:22
User entered 'Yes (Y)'	System	25 Sep 2020 08:58:22

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '281c5c51-0ead-43d4-ae64-9844cec5a4d4'	System	25 Sep 2020 08:58:22
User entered '97.0'	System	25 Sep 2020 08:58:22

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:13', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '281c5c51-0ead-43d4-ae64-9844cec5a4d4'	System	25 Sep 2020 08:58:22
User entered 'No (N)'	System	25 Sep 2020 08:58:22

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:17', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '281c5c51-0ead-43d4-ae64-9844cec5a4d4'	System	25 Sep 2020 08:58:22
User entered '25 Sep 2020 04:58'	System	25 Sep 2020 08:58:22

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 3'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c172efed-9394-4f98-bd98-3ffeea82ea04'	System	26 Sep 2020 00:04:47
User entered 'Yes (Y)'	System	26 Sep 2020 00:04:47

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c172efed-9394-4f98-bd98-3ffeea82ea04'	System	26 Sep 2020 00:04:47
User entered '97.0'	System	26 Sep 2020 00:04:47

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:42', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c172efed-9394-4f98-bd98-3ffeea82ea04'	System	26 Sep 2020 00:04:47
User entered 'No (N)'	System	26 Sep 2020 00:04:47

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:45', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c172efed-9394-4f98-bd98-3ffeea82ea04'	System	26 Sep 2020 00:04:47
User entered '25 Sep 2020 20:04'	System	26 Sep 2020 00:04:47

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 4'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '63fe2af6-634f-434b-8a67-39e9fd350c3b'	System	26 Sep 2020 20:40:23
User entered 'Yes (Y)'	System	26 Sep 2020 20:40:23

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:15', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '63fe2af6-634f-434b-8a67-39e9fd350c3b'	System	26 Sep 2020 20:40:23
User entered '97.0'	System	26 Sep 2020 20:40:23

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:17', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '63fe2af6-634f-434b-8a67-39e9fd350c3b'	System	26 Sep 2020 20:40:23
User entered 'No (N)'	System	26 Sep 2020 20:40:23

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:21', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '63fe2af6-634f-434b-8a67-39e9fd350c3b'	System	26 Sep 2020 20:40:23
User entered '26 Sep 2020 16:40'	System	26 Sep 2020 20:40:23

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 5'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:09', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4f8ffc09-2174-4a62-8ddd-8fdf28d6c652'	System	27 Sep 2020 23:56:42
User entered 'Yes (Y)'	System	27 Sep 2020 23:56:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:33', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4f8ffc09-2174-4a62-8ddd-8fdf28d6c652'	System	27 Sep 2020 23:56:42
User entered '97.0'	System	27 Sep 2020 23:56:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:36', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4f8ffc09-2174-4a62-8ddd-8fdf28d6c652'	System	27 Sep 2020 23:56:42
User entered 'No (N)'	System	27 Sep 2020 23:56:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '4f8ffc09-2174-4a62-8ddd-8fdf28d6c652'	System	27 Sep 2020 23:56:42
User entered '27 Sep 2020 19:56'	System	27 Sep 2020 23:56:42

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 6'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 7'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:21', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'dd4f0f4b-ffd2-4609-9533-0c8332d1af60'	System	30 Sep 2020 11:26:33
User entered 'Yes (Y)'	System	30 Sep 2020 11:26:33

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:25', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'dd4f0f4b-ffd2-4609-9533-0c8332d1af60'	System	30 Sep 2020 11:26:33
User entered '97.0'	System	30 Sep 2020 11:26:33

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:28', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'dd4f0f4b-ffd2-4609-9533-0c8332d1af60'	System	30 Sep 2020 11:26:33
User entered 'No (N)'	System	30 Sep 2020 11:26:33

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:31', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'dd4f0f4b-ffd2-4609-9533-0c8332d1af60'	System	30 Sep 2020 11:26:33
User entered '30 Sep 2020 07:26'	System	30 Sep 2020 11:26:33

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ed009551-96b8-4624-8151-3c896b085d9b'	System	23 Sep 2020 14:40:39
User entered 'None (1)'	System	23 Sep 2020 14:40:39

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ed009551-96b8-4624-8151-3c896b085d9b'	System	23 Sep 2020 14:40:39
User entered 'No (N)'	System	23 Sep 2020 14:40:39

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:31', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ed009551-96b8-4624-8151-3c896b085d9b'	System	23 Sep 2020 14:40:39
User entered 'No (N)'	System	23 Sep 2020 14:40:39

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ed009551-96b8-4624-8151-3c896b085d9b'	System	23 Sep 2020 14:40:39
User entered 'None (1)'	System	23 Sep 2020 14:40:39

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:37', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ed009551-96b8-4624-8151-3c896b085d9b'	System	23 Sep 2020 14:40:39
User entered '23 Sep 2020 10:40'	System	23 Sep 2020 14:40:39

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 10:28'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:58'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8edc170d-1fb5-4d7b-8209-8eb66553a5a0'	System	23 Sep 2020 23:38:04
User entered 'None (1)'	System	23 Sep 2020 23:38:04

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8edc170d-1fb5-4d7b-8209-8eb66553a5a0'	System	23 Sep 2020 23:38:04
User entered 'No (N)'	System	23 Sep 2020 23:38:04

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:48', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8edc170d-1fb5-4d7b-8209-8eb66553a5a0'	System	23 Sep 2020 23:38:04
User entered 'No (N)'	System	23 Sep 2020 23:38:04

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8edc170d-1fb5-4d7b-8209-8eb66553a5a0'	System	23 Sep 2020 23:38:04
User entered 'None (1)'	System	23 Sep 2020 23:38:04

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:37:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '8edc170d-1fb5-4d7b-8209-8eb66553a5a0'	System	23 Sep 2020 23:38:04
User entered '23 Sep 2020 19:37'	System	23 Sep 2020 23:38:04

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 13:53'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 2'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:23', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb1bd78a-a434-4094-88cf-5c6d15837ea6'	System	25 Sep 2020 08:58:38
User entered 'None (1)'	System	25 Sep 2020 08:58:38

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:26', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb1bd78a-a434-4094-88cf-5c6d15837ea6'	System	25 Sep 2020 08:58:38
User entered 'No (N)'	System	25 Sep 2020 08:58:38

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:28', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb1bd78a-a434-4094-88cf-5c6d15837ea6'	System	25 Sep 2020 08:58:38
User entered 'No (N)'	System	25 Sep 2020 08:58:38

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:31', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb1bd78a-a434-4094-88cf-5c6d15837ea6'	System	25 Sep 2020 08:58:38
User entered 'None (1)'	System	25 Sep 2020 08:58:38

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:33', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb1bd78a-a434-4094-88cf-5c6d15837ea6'	System	25 Sep 2020 08:58:38
User entered '25 Sep 2020 04:58'	System	25 Sep 2020 08:58:38

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 3'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:49', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1b39ff8-5db5-4e61-aacb-ef801296df33'	System	26 Sep 2020 00:05:02
User entered 'None (1)'	System	26 Sep 2020 00:05:02

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:51', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1b39ff8-5db5-4e61-aacb-ef801296df33'	System	26 Sep 2020 00:05:02
User entered 'No (N)'	System	26 Sep 2020 00:05:02

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:55', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1b39ff8-5db5-4e61-aacb-ef801296df33'	System	26 Sep 2020 00:05:02
User entered 'No (N)'	System	26 Sep 2020 00:05:02

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:57', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1b39ff8-5db5-4e61-aacb-ef801296df33'	System	26 Sep 2020 00:05:02
User entered 'None (1)'	System	26 Sep 2020 00:05:02

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:04:59', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c1b39ff8-5db5-4e61-aacb-ef801296df33'	System	26 Sep 2020 00:05:02
User entered '25 Sep 2020 20:04'	System	26 Sep 2020 00:05:02

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 4'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:25', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd375489b-f644-4f08-9d4b-048b0a7b769a'	System	26 Sep 2020 20:40:37
User entered 'None (1)'	System	26 Sep 2020 20:40:37

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:27', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd375489b-f644-4f08-9d4b-048b0a7b769a'	System	26 Sep 2020 20:40:37
User entered 'No (N)'	System	26 Sep 2020 20:40:37

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:29', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd375489b-f644-4f08-9d4b-048b0a7b769a'	System	26 Sep 2020 20:40:37
User entered 'No (N)'	System	26 Sep 2020 20:40:37

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:32', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd375489b-f644-4f08-9d4b-048b0a7b769a'	System	26 Sep 2020 20:40:37
User entered 'None (1)'	System	26 Sep 2020 20:40:37

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:34', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'd375489b-f644-4f08-9d4b-048b0a7b769a'	System	26 Sep 2020 20:40:37
User entered '26 Sep 2020 16:40'	System	26 Sep 2020 20:40:37

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 5'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:42', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ce24bc09-9050-4c44-b2eb-b789624f2cb9'	System	27 Sep 2020 23:56:53
User entered 'None (1)'	System	27 Sep 2020 23:56:53

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:44', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ce24bc09-9050-4c44-b2eb-b789624f2cb9'	System	27 Sep 2020 23:56:53
User entered 'No (N)'	System	27 Sep 2020 23:56:53

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ce24bc09-9050-4c44-b2eb-b789624f2cb9'	System	27 Sep 2020 23:56:53
User entered 'No (N)'	System	27 Sep 2020 23:56:53

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:47', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ce24bc09-9050-4c44-b2eb-b789624f2cb9' User entered 'None (1)'	System	27 Sep 2020 23:56:53
	System	27 Sep 2020 23:56:53

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:51', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'ce24bc09-9050-4c44-b2eb-b789624f2cb9' User entered '27 Sep 2020 19:56'	System	27 Sep 2020 23:56:53
	System	27 Sep 2020 23:56:53

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 6'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 7'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:35', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '88bc2e4b-15c1-4859-9ada-84d8374c3185'	System	30 Sep 2020 11:26:54
User entered 'None (1)'	System	30 Sep 2020 11:26:54

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '88bc2e4b-15c1-4859-9ada-84d8374c3185'	System	30 Sep 2020 11:26:54
User entered 'No (N)'	System	30 Sep 2020 11:26:54

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '88bc2e4b-15c1-4859-9ada-84d8374c3185'	System	30 Sep 2020 11:26:54
User entered 'No (N)'	System	30 Sep 2020 11:26:54

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:50', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '88bc2e4b-15c1-4859-9ada-84d8374c3185'	System	30 Sep 2020 11:26:54
User entered 'None (1)'	System	30 Sep 2020 11:26:54

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '88bc2e4b-15c1-4859-9ada-84d8374c3185'	System	30 Sep 2020 11:26:54
User entered '30 Sep 2020 07:26'	System	30 Sep 2020 11:26:54

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c'	System	23 Sep 2020 14:41:02
User entered 'None (0)'	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c'	System	23 Sep 2020 14:41:02
User entered 'None (0)'	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:49', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c'	System	23 Sep 2020 14:41:02
User entered 'None (0)'	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:51', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c'	System	23 Sep 2020 14:41:02
User entered 'None (0)'	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:53', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c'	System	23 Sep 2020 14:41:02
User entered 'None (0)'	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:55', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c'	System	23 Sep 2020 14:41:02
User entered 'None (0)'	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:40:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c'	System	23 Sep 2020 14:41:02
User entered 'No (N)'	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T10:41:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'c3c574fd-3c4f-4eb4-a256-dfeddb1a313c'	System	23 Sep 2020 14:41:02
User entered '23 Sep 2020 10:41'	System	23 Sep 2020 14:41:02

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 10:28'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:58'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:07', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118'	System	23 Sep 2020 23:38:25
User entered 'None (0)'	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:08', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118'	System	23 Sep 2020 23:38:25
User entered 'None (0)'	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118'	System	23 Sep 2020 23:38:25
User entered 'None (0)'	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:12', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118'	System	23 Sep 2020 23:38:25
User entered 'None (0)'	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:14', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118'	System	23 Sep 2020 23:38:25
User entered 'None (0)'	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:16', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118'	System	23 Sep 2020 23:38:25
User entered 'None (0)'	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:20', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118'	System	23 Sep 2020 23:38:25
User entered 'No (N)'	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-23T19:38:22', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '9a54242f-28c4-4bbf-9a1b-bc608564f118'	System	23 Sep 2020 23:38:25
User entered '23 Sep 2020 19:38'	System	23 Sep 2020 23:38:25

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 13:53'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 2'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:36', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c'	System	25 Sep 2020 08:59:01
User entered 'None (0)'	System	25 Sep 2020 08:59:01

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c'	System	25 Sep 2020 08:59:01
User entered 'None (0)'	System	25 Sep 2020 08:59:01

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:44', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c'	System	25 Sep 2020 08:59:01
User entered 'None (0)'	System	25 Sep 2020 08:59:01

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:50', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c'	System	25 Sep 2020 08:59:01
User entered 'None (0)'	System	25 Sep 2020 08:59:01

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:52', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c'	System	25 Sep 2020 08:59:01
User entered 'None (0)'	System	25 Sep 2020 08:59:01

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:54', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c'	System	25 Sep 2020 08:59:01
User entered 'None (0)'	System	25 Sep 2020 08:59:01

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:57', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c'	System	25 Sep 2020 08:59:01
User entered 'No (N)'	System	25 Sep 2020 08:59:01

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T04:58:59', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '5379b556-9722-46f5-bc79-7bfa460df62c'	System	25 Sep 2020 08:59:01
User entered '25 Sep 2020 04:58'	System	25 Sep 2020 08:59:01

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 3'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504'	System	26 Sep 2020 00:05:20
User entered 'None (0)'	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:04', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504'	System	26 Sep 2020 00:05:20
User entered 'None (0)'	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:05', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504'	System	26 Sep 2020 00:05:20
User entered 'None (0)'	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:07', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504'	System	26 Sep 2020 00:05:20
User entered 'None (0)'	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:08', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504'	System	26 Sep 2020 00:05:20
User entered 'None (0)'	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:09', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504'	System	26 Sep 2020 00:05:20
User entered 'None (0)'	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:15', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504'	System	26 Sep 2020 00:05:20
User entered 'No (N)'	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-25T20:05:17', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'a0f6aede-df7b-49a5-9684-cd938a7d0504'	System	26 Sep 2020 00:05:20
User entered '25 Sep 2020 20:05'	System	26 Sep 2020 00:05:20

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 4'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:38', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1'	System	26 Sep 2020 20:40:54
User entered 'None (0)'	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:39', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1'	System	26 Sep 2020 20:40:54
User entered 'None (0)'	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:41', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1'	System	26 Sep 2020 20:40:54
User entered 'None (0)'	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:42', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1'	System	26 Sep 2020 20:40:54
User entered 'None (0)'	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:43', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1'	System	26 Sep 2020 20:40:54
User entered 'None (0)'	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:45', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1'	System	26 Sep 2020 20:40:54
User entered 'None (0)'	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:49', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1'	System	26 Sep 2020 20:40:54
User entered 'No (N)'	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-26T16:40:51', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '364f1c49-e26d-4e63-bbe7-43a8a70a2ef1'	System	26 Sep 2020 20:40:54
User entered '26 Sep 2020 16:40'	System	26 Sep 2020 20:40:54

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 5'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:56', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f'	System	27 Sep 2020 23:57:15
User entered 'None (0)'	System	27 Sep 2020 23:57:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:56:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f'	System	27 Sep 2020 23:57:15
User entered 'None (0)'	System	27 Sep 2020 23:57:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:01', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f'	System	27 Sep 2020 23:57:15
User entered 'None (0)'	System	27 Sep 2020 23:57:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:02', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f' User entered 'None (0)'	System	27 Sep 2020 23:57:15
	System	27 Sep 2020 23:57:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:05', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f'	System	27 Sep 2020 23:57:15
User entered 'None (0)'	System	27 Sep 2020 23:57:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:07', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f'	System	27 Sep 2020 23:57:15
User entered 'None (0)'	System	27 Sep 2020 23:57:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:11', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f'	System	27 Sep 2020 23:57:15
User entered 'No (N)'	System	27 Sep 2020 23:57:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-27T19:57:13', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: 'bb497fe9-3f89-4358-b8b9-67d72c9fbd9f'	System	27 Sep 2020 23:57:15
User entered '27 Sep 2020 19:57'	System	27 Sep 2020 23:57:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 6'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 14:25:34
User entered 'Day 7'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:56', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'None (0)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:26:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'None (0)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:00', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'None (0)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:01', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'None (0)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:03', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79'	System	30 Sep 2020 11:27:15
User entered 'None (0)'	System	30 Sep 2020 11:27:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:05', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79' User entered 'None (0)'	System	30 Sep 2020 11:27:15
	System	30 Sep 2020 11:27:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:10', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79'	System	30 Sep 2020 11:27:15
User entered 'No (N)'	System	30 Sep 2020 11:27:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-09-30T07:27:12', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '0f2f11ad-519d-421c-9326-873969f34e79'	System	30 Sep 2020 11:27:15
User entered '30 Sep 2020 07:27'	System	30 Sep 2020 11:27:15

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:25:34

US3692016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:11:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:25:34

US3692016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexander Bradley (b) (4)	30 Sep 2020 13:56:00
	(b) (4)	

US3692016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Alexander Bradley (b) (4) (b) (4)	30 Sep 2020 13:56:00

US3692016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexander Bradley (b) (4)	30 Sep 2020 13:56:00

US3692016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'participant reports no health changes. plans to get flu vaccine on 10/15/20.' reason for change: Data Entry Error	Abigail Riddick (b) (4)	09 Oct 2020 16:52:11
User entered empty.	Alexander Bradley (b) (4)	30 Sep 2020 13:56:00

US3692016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexander Bradley (b) (4)	30 Sep 2020 13:56:04
	(b) (4)	

US3692016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 13:56:04

US3692016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patti Vasquez (b) (4) (b) (4)	07 Oct 2020 17:44:21

US3692016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Patti Vasquez (b) (4) (b) (4)	07 Oct 2020 17:44:21

US3692016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Patti Vasquez (b) (4) (b) (4)	07 Oct 2020 17:44:21

US3692016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'participant reports no changes since last contact by study.' reason for change: Data Entry Error	Abigail Riddick (b) (4)	09 Oct 2020 16:52:52
User entered empty.	Patti Vasquez (b) (4)	07 Oct 2020 17:44:21

US3692016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Patti Vasquez (b) (4) (b) (4)	07 Oct 2020 17:44:27

US3692016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 17:44:27

US3692016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 21:01:51

US3692016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 21:01:51

US3692016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Oct 2020 21:01:51

US3692016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Rosuvastatin changed from QOD to twice weekly'	(b) (4), (b) (6)	15 Oct 2020 21:01:51

US3692016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 21:01:56

US3692016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 21:01:56

US3692016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:14

US3692016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:14

US3692016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:14

US3692016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:11:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	23 Oct 2020 23:19:14

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '8:03'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '23 Oct 2020 8:03'	System	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '16'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '119'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '69'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:11:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 23:19:45

US3692016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:49

US3692016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:11:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:19:49

US3692016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:20:05

US3692016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:20:05

US3692016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '8:36'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:20:05

US3692016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '23 Oct 2020 8:36'	System	23 Oct 2020 23:20:05

US3692016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:20:10

US3692016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 23:20:10

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered 'Day 78'	System	29 Aug 2020 15:50:09

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:07', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352'	System	12 Nov 2020 13:23:14
User entered 'Yes (Y)'	System	12 Nov 2020 13:23:14

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

Have you been exposed to someone with 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 (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:11', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352'	System	12 Nov 2020 13:23:14
User entered 'No (N)'	System	12 Nov 2020 13:23:14

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:15', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352'	System	12 Nov 2020 13:23:14
User entered 'No (N)'	System	12 Nov 2020 13:23:14

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:30', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352'	System	12 Nov 2020 13:23:14
User entered 'Yes (Y)'	System	12 Nov 2020 13:23:14

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:46', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352'	System	12 Nov 2020 13:23:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 13:23:14

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (872586CE-C864-4B79-9E24-814B3B13FC1D)', Time: '2020-11-12T08:22:58', User OID: 'PatientReportedOutcome (US3692016)', ODM File OID: '197cd08b-db23-4a03-a7b6-eb8ef4a37352' User entered '12 Nov 2020 08:22:58'	System	12 Nov 2020 13:23:14
	System	12 Nov 2020 13:23:14

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered '12 Nov 2020 00:01'	System	29 Aug 2020 15:50:09

US3692016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:50:09
User entered '16 Nov 2020 23:59'	System	29 Aug 2020 15:50:09

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Oct 2020 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 Oct 2020 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '02 Nov 2020 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '06 Nov 2020 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '09 Nov 2020 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '13 Nov 2020 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '24 Oct 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '28 Oct 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '31 Oct 2022 00:01'	System	19 Nov 2020 19:53:36

US3692016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:11:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:53:36
Amendment Manager: User entered '04 Nov 2022 23:59'	System	19 Nov 2020 19:53:36

US3692016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 14:55:22

US3692016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered '17 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 14:55:22

US3692016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Nov 2020 14:55:22

US3692016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:11:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 14:55:22

US3692016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 14:55:32

US3692016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:11:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 14:55:32

US3692016

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:11:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:14:58

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 23:17:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 23:17:42
Data point term sent to Coder	System	23 Oct 2020 23:16:27
User entered 'hypertension'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '29 Aug 2020'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 23:17:13
User entered '12:14' reason for change: Data Entry Error	Kristi Kirkland (b) (4)	23 Oct 2020 23:17:13
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 23:16:09
User entered empty.	Kristi Kirkland (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:14'	System	23 Oct 2020 23:17:13
User entered empty.	System	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4)	23 Oct 2020 23:16:09
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '23 Sep 2020'	Kristi Kirkland (b) (4)	23 Oct 2020 23:16:09
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User closed query 'Per CDM: Per page 33 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V1D1). Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:07:28
User entered '08:18' reason for change: Data Entry Error	Mandy Tipton (b) (4)	03 Nov 2020 01:21:26
Query 'Per CDM: Per page 33 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V1D1). Please consider it to remove. Thank you. ' answered with '2nd dose was 23SEP2020, so it is required at this data point.' (Site from DM).	Mandy Tipton (b) (4)	03 Nov 2020 01:21:16
User opened query 'Per CDM: Per page 33 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V1D1). Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 03:22:02
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 23:17:13
User entered '8:18' reason for change: Data Entry Error	Kristi Kirkland (b) (4)	23 Oct 2020 23:17:13
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 23:16:09
User entered empty.	Kristi Kirkland (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 08:18'	System	03 Nov 2020 01:21:26
User entered '23 Sep 2020 8:18'	System	23 Oct 2020 23:17:13
User entered empty.	System	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4)	23 Oct 2020 23:16:09
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4)	23 Oct 2020 23:16:09
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Related (NOT RELATED)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Related (NOT RELATED)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'None (NONE)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '1'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:11:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 23:16:09

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 06:06:05
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Participant was assessed for COVID-19, per protocol.' (Site from DM).	Erin Cardot (b) (4) (b) (4)	19 Nov 2020 14:29:57
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:04:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Tachypnoea, LLT: Tachypnea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 23:19:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 23:19:38
Data point term sent to Coder	System	23 Oct 2020 23:18:31
User entered 'tachypnea'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '23 Sep 2020'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:28:43
User closed query 'Per CDM: Requery: Response noted, however start time is prior to dosing time(V2D29).which is not within 24 hrs of dosing time (post dose).Please consider it to remove. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:14:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:13:47
Query 'Data is required. Please provide.' answered with 'Updated.' (Site from System).	Mandy Tipton (b) (4)	10 Nov 2020 21:54:04
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 21:53:52
DataPoint Un-verified.	Mandy Tipton (b) (4)	10 Nov 2020 21:53:52
User entered empty; reason for change Data Entry Error	Mandy Tipton (b) (4)	10 Nov 2020 21:53:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
Query 'Per CDM: Requery: Response noted, however start time is prior to dosing time(V2D29).which is not within 24 hrs of dosing time (post dose).Please consider it to remove. Thank you.' answered with 'VS measurement taken at Day 29 visit, within 24 hours of IP.' (Site from DM).	Maria Stetson (b) (4)	10 Nov 2020 14:27:29
User opened query 'Per CDM: Requery: Response noted, however start time is prior to dosing time(V2D29).which is not within 24 hrs of dosing time (post dose).Please consider it to remove. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:21:19
User closed query 'Per CDM: Per page 33 of CCGs, This field is not required, unless Start time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:16:49
Query 'Per CDM: Per page 33 of CCGs, This field is not required, unless Start time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you. ' answered with 'Data point is within 24hrs of the 2nd vaccination.' (Site from DM).	Mandy Tipton (b) (4)	03 Nov 2020 01:22:26
User entered '08:18' reason for change: Data Entry Error	Mandy Tipton (b) (4)	03 Nov 2020 01:22:20

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per page 33 of CCGs, This field is not required, unless Start time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you. ' (Site from DM). User entered '8:18'	(b) (4), (b) (6)	02 Nov 2020 03:26:04
	Kristi Kirkland (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:53:52
User entered '23 Sep 2020 08:18'	System	03 Nov 2020 01:22:20
User entered '23 Sep 2020 8:18'	System	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '23 Oct 2020'	Kristi Kirkland (b) (4)	23 Oct 2020 23:18:27
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:28:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 05:32:29
User closed query 'Per CDM: Requery: Response noted, however, this field is not required as it is not within 24 hrs of dosing time. Please consider it to remove. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:32:26
Query 'Data is required. Please provide.' answered with 'Time is not required. ' (Site from System).	Mandy Tipton (b) (4)	10 Nov 2020 21:54:26
Query 'Per CDM: Requery: Response noted, however, this field is not required as it is not within 24 hrs of dosing time. Please consider it to remove. Thank you.' answered with 'Updated. ' (Site from DM).	Mandy Tipton (b) (4)	10 Nov 2020 21:54:15
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 21:53:52
DataPoint Un-verified.	Mandy Tipton (b) (4)	10 Nov 2020 21:53:52
User entered empty; reason for change Data Entry Error	Mandy Tipton (b) (4)	10 Nov 2020 21:53:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User opened query 'Per CDM: Requery: Response noted, however, this field is not required as it is not within 24 hrs of dosing time. Please consider it to remove. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:28:05
User closed query 'Per CDM: Per page 33 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:22:26
User entered '08:03' reason for change: Data Entry Error	Mandy Tipton (b) (4)	03 Nov 2020 01:22:44
Query 'Per CDM: Per page 33 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you.' answered with 'Data point is within 24hrs of the 2nd vaccination.' (Site from DM).	Mandy Tipton (b) (4)	03 Nov 2020 01:22:37

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User opened query ' Per CDM: Per page 33 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V2D29). Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 03:27:05
User entered '8:03'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:53:52
User entered '23 Oct 2020 08:03'	System	03 Nov 2020 01:22:44
User entered '23 Oct 2020 8:03'	System	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Related (NOT RELATED)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Related (NOT RELATED)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'None (NONE)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '1'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:11:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 23:18:27

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:36:15
User entered 'USA-US123-2020-mRNA-1273-P301000001'	System	03 Nov 2020 20:35:35
User entered 'New'	(b) (4), (b) (6)	03 Nov 2020 20:35:35

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User coded data point as SOC: Vascular disorders, HLT: Aneurysms and artery dissections, HLT: Peripheral aneurysms and dissections, PT: Peripheral artery aneurysm, LLT: Iliac artery aneurysm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 01:43:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 01:43:11
Data point term sent to Coder	System	03 Nov 2020 01:42:24
User entered 'iliac artery aneurysm'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '01 Nov 2020'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:27:09
DataPoint Un-verified.	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
User entered 'No (N)' reason for change: New Information	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Yes (Y)'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Maria Stetson (b) (4)	17 Nov 2020 20:37:56
	(b) (4)	
User entered '02 Nov 2020' reason for change: New Information	Maria Stetson (b) (4)	17 Nov 2020 20:37:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:27:11
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Nov 2020 21:52:57
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Nov 2020 21:52:57
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Nov 2020 21:52:30
DataPoint Un-verified.	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
	(b) (4)	
User entered '08 Nov 2020' reason for change: New Information	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:27:13
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:38:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please keep this query open until Discharge date is recorded. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:33:35
Query 'Per CDM: Please keep this query open until Discharge date is recorded. Thank you.' answered with 'Resolved.' (Site from DM).	Mandy Tipton (b) (4)	10 Nov 2020 21:53:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User opened query 'Per CDM: Please keep this query open until Discharge date is recorded. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:42:52
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 06:37:55
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Discharge date pending.' (Site from System).	Mandy Tipton (b) (4)	03 Nov 2020 01:42:45
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	03 Nov 2020 01:41:56
User entered '1'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '01 Nov 2020'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:28:43
DataPoint Un-verified.	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
User entered '08 Nov 2020' reason for change: New Information	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:28:30
DataPoint Un-verified.	Mandy Tipton (b) (4)	10 Nov 2020 21:52:30
User entered '4' reason for change: New Information	(b) (4)	10 Nov 2020 21:52:30
DataPoint Verified.	Mandy Tipton (b) (4)	10 Nov 2020 16:32:01
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Maria Stetson (b) (4)	17 Nov 2020 20:37:56
	(b) (4)	
User entered '1' reason for change: New Information	Maria Stetson (b) (4)	17 Nov 2020 20:37:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Related (NOT RELATED)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Related (NOT RELATED)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Not Applicable (NOT APPLICABLE)'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '0'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '1'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered '1'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:28:43
DataPoint Un-verified.	Mandy Tipton (b) (4)	10 Nov 2020 21:52:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mandy Tipton (b) (4)	10 Nov 2020 21:52:57
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mandy Tipton (b) (4)	03 Nov 2020 01:41:56
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered empty.	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 13:55:41
User closed query 'PV Query: Please confirm this event meets SAE reporting guidelines, it was reported the aneurysm was from a finding in 2017. If this was a planned, elective procedure, then please consider deleting as an SAE.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 13:55:39
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'N/A.' (Site from Safety).	Maria Stetson (b) (4)	16 Nov 2020 14:49:28
Query 'PV Query: Please confirm this event meets SAE reporting guidelines, it was reported the aneurysm was from a finding in 2017. If this was a planned, elective procedure, then please consider deleting as an SAE.' answered with 'Consistent with SAE reporting criteria as outlined on page 74 of Protocol Amendment 4, due to inpatient hospitalization, requiring overnight stay.' (Site from Safety).	Maria Stetson (b) (4)	16 Nov 2020 13:14:21
User entered 'ADMITTED FOR ELECTIVE OPEN REPAIR OF 3.7CM RIGHT ILIAC ANEURYSM, WHICH WAS AN INCIDENTAL FINDING IN 2017. REPAIR WENT WELL AND STAYED IN HOSPITAL POST-SURGERY FOR PAIN MANAGEMENT. DISCHARGED WITHOUT COMPLICATIONS ON 08-NOVEMBER-2020. Consistent with SAE reporting criteria as outlined on page 74 of Protocol Amendment 4, due to inpatient hospitalization.' reason for change: New Information DataPoint Un-verified.	Maria Stetson (b) (4)	16 Nov 2020 13:14:02
	(b) (4)	
User entered 'ADMITTED FOR ELECTIVE OPEN REPAIR OF 3.7CM RIGHT ILIAC ANEURYSM, WHICH WAS AN INCIDENTAL FINDING IN 2017. REPAIR WENT WELL AND Stayed in hospital post-surgery FOR PAIN MANAGEMENT. Discharged without complications on 08-November-2020.' reason for change: New Information	Maria Stetson (b) (4)	16 Nov 2020 13:13:26
	(b) (4)	

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 18:08:41
User opened query 'PV Query: Please confirm this event meets SAE reporting guidelines, it was reported the aneurysm was from a finding in 2017. If this was a planned, elective procedure, then please consider deleting as an SAE.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 18:08:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:01
User entered 'Admitted for elective open repair of 3.7cm right iliac aneurysm, which was an incidental finding in 2017. Repair went well and remains admitted for pain management. Updates to follow.'	Mandy Tipton (b) (4) (b) (4)	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 01:41:56

US3692016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:11:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 01:41:56

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:11:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:32:34
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:13:57
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:18:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:18:44
Data point term sent to Coder	System	01 Sep 2020 18:18:14
User entered 'singulair'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:17:26

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'reactive-airway disease'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '10'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2017'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 18:21:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 18:21:10
User entered 'No (N)' reason for change: Data Entry Error	Abigail Riddick (b) (4)	01 Sep 2020 18:21:10
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 18:17:26
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:17:26

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:17:26

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:17:26

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:17:26

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE, PRODUCTSYNONYM: ZETIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:23:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:23:57
Data point term sent to Coder	System	01 Sep 2020 18:23:27
User entered 'zetia'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:23:17

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'secondary prevention for cardiovascular disease'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:23:17

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '10'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2017'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:23:17
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:23:17

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:23:17

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:23:17

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:18:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:18:52
Data point term sent to Coder	System	01 Sep 2020 18:27:39
User entered 'rosuvastatin'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:27:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User closed query 'Per CDM Re-Query: Thank you for your confirmation. Please make sure it is included in the Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:39:40
Query 'Per CDM Re-Query: Thank you for your confirmation. Please make sure it is included in the Medical History. Thank you' answered with 'documented' (Site from DM).	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:12:24
User opened query 'Per CDM Re-Query: Thank you for your confirmation. Please make sure it is included in the Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:14:09
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:14:09
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'confirmed' (Site from DM).	Kristi Kirkland (b) (4) (b) (4)	10 Oct 2020 17:06:49
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 02:52:11
User entered 'slow progression of atherosclerosis'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:27:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '5'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'every other day (QOD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un Jun 2019'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)' reason for change: Data Entry Error	Kristi Kirkland (b) (4)	18 Oct 2020 13:57:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '12 Oct 2020' reason for change: Data Entry Error	Kristi Kirkland (b) (4)	18 Oct 2020 13:57:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:27:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:27:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 18:27:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:27:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
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: BUDESONIDE, PRODUCTSYNONYM: PULMICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:34:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:34:50
Data point term sent to Coder	System	01 Sep 2020 18:31:52
User entered '(budesonide) pulmicort inhaler'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:31:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'reactive airway disease'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '2'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'puff (PUFF)'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'twice daily (BID)'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:31:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2000'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:31:08
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 18:31:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:31:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:31:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:30:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:30:37
Data point term sent to Coder	System	01 Sep 2020 18:33:58
User entered 'glucosamine - chondroitin capsule'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:33:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'joint health'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '1500/200'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:33:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:33:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:33:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:33:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ALLIUM SATIVUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:30:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:30:36
Data point term sent to Coder	System	01 Sep 2020 18:36:08
User entered 'garlic'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:35:20

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'heart health'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'unknown'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'capsule (CAPSULE)'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:35:20

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:35:20
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:35:20

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:35:20

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:35:20

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:02:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:02:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 09:31:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 09:31:43
Data point term sent to Coder	System	01 Sep 2020 18:41:21
User entered 'tumeric capsule'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:41:11

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'joint health'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '1350'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'twice daily (BID)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:41:11
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 18:41:11

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:41:11

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:41:11

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:43:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:43:50
Data point term sent to Coder	System	01 Sep 2020 18:42:26
User entered 'aspirin'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:42:24

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'heart health'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '81'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2017'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:42:24
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:42:24

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:42:24

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:42:24

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 09:17:57
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 Sep 2020 09:17:57
Data point term sent to Coder	System	01 Sep 2020 18:44:32
User entered 'multivitamin for men'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:43:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'health promotion'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '1'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'tablet (TABLET)'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:43:37
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:43:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:43:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:43:37

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 00:25:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 00:25:36
Data point term sent to Coder	System	01 Sep 2020 18:57:06
User entered 'fish oil capsules'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:56:12

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'health promotion'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '1400'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'twice daily (BID)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:56:12
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 18:56:12

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:56:12

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:56:12

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: ZINGIBER OFFICINALE, PRODUCTSYNONYM: GINGER [ZINGIBER OFFICINALE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 00:54:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 00:54:02
Data point term sent to Coder	System	01 Sep 2020 18:58:12
User entered 'ginger'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:57:21

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'heart health'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '1'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'capsule (CAPSULE)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:57:21
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:57:21

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:57:21

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:57:21

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CITRATE;COLECALCIFEROL, PRODUCTSYNONYM: CITRACAL [CALCIUM CITRATE;COLECALCIFEROL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 12:01:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 12:01:41
Data point term sent to Coder	System	08 Sep 2020 19:44:54
User closed 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).	System	08 Sep 2020 19:44:48
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.' answered with 'Updated. ' (Site from System).	Mandy Tipton (b) (4) (b) (4)	08 Sep 2020 19:44:48
User entered 'CITRACAL (calcium and vitamin D3)' reason for change: Per Query Resolution	Mandy Tipton (b) (4) (b) (4)	08 Sep 2020 19:44:40
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) (b) (4)	07 Sep 2020 12:17:47
Data point term sent to Coder	System	01 Sep 2020 18:59:15
User entered 'citracal'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:58:36

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'bone health'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User closed query 'Per CDM Re-Query: Please confirm if dose can not be obtained. as this ConMed is marked On-Going. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:41:38
Query 'Per CDM Re-Query: Please confirm if dose can not be obtained. as this ConMed is marked On-Going. Thank you' answered with 'confirmed' (Site from DM).	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 23:12:51
User opened query 'Per CDM Re-Query: Please confirm if dose can not be obtained. as this ConMed is marked On-Going. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:15:29
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:15:29
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' answered with 'unk dose ' (Site from DM).	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:56:38
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 02:50:45
User entered '1'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:58:36

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'tablet (TABLET)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:58:36
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:58:36

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:58:36

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:58:36

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COENZYME Q10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:12:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:12:38
Data point term sent to Coder	System	01 Sep 2020 19:00:16
User entered 'coenzyme q10'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:59:48

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'heart health'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '400'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'every other day (QOD)'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'un UNK 2010'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 18:59:48

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Abigail Riddick (b) (4)	01 Sep 2020 18:59:48
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:59:48

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 18:59:48

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:59:48

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 13:59:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 13:59:19
Data point term sent to Coder	System	18 Oct 2020 13:59:11
User entered 'lisinopril'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'hypertension'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '5'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'once daily (QD)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '21 Sep 2020'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Oct 2020 13:59:08

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 14:47:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 14:47:25
Data point term sent to Coder	System	18 Oct 2020 14:00:11
User entered 'rosuvastatin'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'hperlipidemia'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '5'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'mg (mg)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'other (OTHER)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '2x a week'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Oral (ORAL)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '12 Oct 2020'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:35:22
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Oct 2020 14:00:09

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
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)	13 Nov 2020 21:16:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:16:37
Data point term sent to Coder	System	13 Nov 2020 21:16:06
User entered 'Tylenol'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Pain (post-bilateral iliac aneurysm repair)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '325'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'mg (mg)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'other (OTHER)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '2 tablets Q6N'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral (ORAL)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '08 Nov 2020'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '0'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:15:15

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:16:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:16:37
Data point term sent to Coder	System	13 Nov 2020 21:16:06
User entered 'Colace'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Stool softner'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '100'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'mg (mg)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'once daily (QD)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral (ORAL)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '08 Nov 2020'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '0'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 21:16:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:38:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:38:35
Data point term sent to Coder	System	13 Nov 2020 21:21:12
User entered 'Dilaudid'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Pain (post bilateral iliac aneurysm repair)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '2'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'mg (mg)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'other (OTHER)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1 tablet prn/Q4 hours for up to 5 days'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral (ORAL)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '08 Nov 2020'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '0'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '13 Nov 2020'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:20:42

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:23:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:23:34
Data point term sent to Coder	System	13 Nov 2020 21:23:14
User entered 'Senokot'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Stimulant Laxative'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '17.2'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'mg (mg)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'twice daily (BID)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral (ORAL)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '08 Nov 2020'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '0'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 21:22:23

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL, PRODUCTSYNONYM: CIALIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:27:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	13 Nov 2020 21:27:35
Data point term sent to Coder	System	13 Nov 2020 21:26:17
User entered 'Cialis'	Maria Stetson (b) (4)	13 Nov 2020 21:25:58
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Erectile dysfunction'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '10'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'mg (mg)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'other (OTHER)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1-2 tablets prn'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral (ORAL)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:25:58

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: CRIES PROPHYLACTIC AGENTS, PRODUCT: SODIUM FLUORIDE, PRODUCTSYNONYM: PREVIDENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:16:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:16:41
Data point term sent to Coder	System	13 Nov 2020 21:36:27
User entered 'Prevident 1.1%'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral hygiene'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Other (OTHER)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'administration'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'once daily (QD)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Other (OTHER)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Oral toothpaste'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 21:36:04

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User closed query 'Please verify. Discharge summary has #23-Clindamycin 1% gel (Clindagel) for acne. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 21:46:04
Query 'Please verify. Discharge summary has #23-Clindamycin 1% gel (Clindagel) for acne. ' answered with 'Updated.' (Site from CRA).	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:14:40
User opened query 'Please verify. Discharge summary has #23-Clindamycin 1% gel (Clindagel) for acne. ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:57:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL, PRODUCTSYNONYM: PREVENTIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:53:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:53:36
Data point term sent to Coder	System	13 Nov 2020 21:37:29
User entered 'Preventil'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Wheezing'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '180'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'ug (ug)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'other (OTHER)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'PRN Q6 hours'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 21:37:16

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:02:58
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 Nov 2020 10:02:58
Data point term sent to Coder Coding entries removed.	System Maria Stetson (b) (4)	17 Nov 2020 16:47:49 17 Nov 2020 16:47:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:46:44
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 19:17:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 19:17:57
Data point term sent to Coder User entered 'clindamycin 1%'	System Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:17:06 16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
	(b) (4)	
User entered 'Folliculitis' reason for change: Data Entry Error	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'acne'	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Other (OTHER)'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'application'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'once daily (QD)'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Topical (TOPICAL)'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
	(b) (4)	
User entered 'UN UNK 2005' reason for change: New Information	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
	(b) (4)	
User entered '0' reason for change: New Information	Maria Stetson (b) (4)	17 Nov 2020 16:47:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered '1'	Mandy Tipton (b) (4)	16 Nov 2020 19:16:34
	(b) (4)	

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered empty.	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:46:44
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:11:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 19:16:34

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:11:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:47:18
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	12 Nov 2020 19:02:15

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:11:21

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:05
User entered '02 Nov 2020'	Mandy Tipton (b) (4) (b) (4)	12 Nov 2020 19:16:39

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:11:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:05
User entered 'open iliac artery repair'	Mandy Tipton (b) (4) (b) (4)	12 Nov 2020 19:16:39

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:11:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:05
User entered 'Medical History (MH)'	Mandy Tipton (b) (4) (b) (4)	12 Nov 2020 19:16:39

US3692016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:11:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:48:05
User entered empty.	Mandy Tipton (b) (4) (b) (4)	12 Nov 2020 19:16:39

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'USA-US123-2020-MRNA-1273-P301000001'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 20:37:56
DataPoint Un-verified.	System	17 Nov 2020 20:37:56
User entered 'Yes (Y)'	System	17 Nov 2020 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Cynthia'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Gay'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '130 Mason Farm Rd, CB #7030'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Chapel Hill'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 13:56:04
DataPoint Un-verified.	System	17 Nov 2020 13:56:04
User entered empty.	System	17 Nov 2020 13:56:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered 'North Carolina'	Mandy Tipton (b) (4)	12 Nov 2020 14:37:41
	(b) (4)	

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '27599-7030'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered 'US'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Nov 2020 23:05:52
User entered '3'	System	17 Nov 2020 13:56:04
User entered '2'	System	12 Nov 2020 00:30:19
User entered '1'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'USA-US123-2020-MRNA-1273-P301000001'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 20:37:56
DataPoint Un-verified.	System	17 Nov 2020 20:37:56
User entered 'Yes (Y)'	System	17 Nov 2020 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Cynthia'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Gay'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '130 Mason Farm Rd, CB #7030'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Chapel Hill'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 13:56:04
DataPoint Un-verified.	System	17 Nov 2020 13:56:04
User entered empty.	System	17 Nov 2020 13:56:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered 'North Carolina'	Mandy Tipton (b) (4)	12 Nov 2020 14:37:41
	(b) (4)	

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '27599-7030'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered 'US'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Nov 2020 23:05:52
User entered '3'	System	17 Nov 2020 13:56:04
User entered '2'	System	12 Nov 2020 00:30:19
User entered '1'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:11:21

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered '03/Nov/2020 20:37'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:11:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'USA-US123-2020-MRNA-1273-P301000001'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 20:37:56
DataPoint Un-verified.	System	17 Nov 2020 20:37:56
User entered 'Yes (Y)'	System	17 Nov 2020 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Cynthia'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Gay'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '130 Mason Farm Rd, CB #7030'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Chapel Hill'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 13:56:04
DataPoint Un-verified.	System	17 Nov 2020 13:56:04
User entered empty.	System	17 Nov 2020 13:56:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered 'North Carolina'	Mandy Tipton (b) (4)	12 Nov 2020 14:37:41
	(b) (4)	

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '27599-7030'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered 'US'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Nov 2020 23:05:52
User entered '3'	System	17 Nov 2020 13:56:04
User entered '2'	System	12 Nov 2020 00:30:19
User entered '1'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:11:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered '11/Nov/2020 19:30'	System	12 Nov 2020 00:30:19

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:11:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 00:30:19

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'USA-US123-2020-MRNA-1273-P301000001'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 20:37:56
DataPoint Un-verified.	System	17 Nov 2020 20:37:56
User entered 'Yes (Y)'	System	17 Nov 2020 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Cynthia'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Gay'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '130 Mason Farm Rd, CB #7030'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Chapel Hill'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 13:56:04
DataPoint Un-verified.	System	17 Nov 2020 13:56:04
User entered empty.	System	17 Nov 2020 13:56:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered 'North Carolina'	Mandy Tipton (b) (4)	12 Nov 2020 14:37:41
	(b) (4)	

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '27599-7030'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered 'US'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Nov 2020 23:05:52
User entered '3'	System	17 Nov 2020 13:56:04
User entered '2'	System	12 Nov 2020 00:30:19
User entered '1'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:11:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '17/Nov/2020 13:56'	System	17 Nov 2020 13:56:04

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:11:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 13:56:04

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'USA-US123-2020-MRNA-1273-P301000001'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Yes (Y)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 20:37:56
DataPoint Un-verified.	System	17 Nov 2020 20:37:56
User entered 'Yes (Y)'	System	17 Nov 2020 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'No (N)'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Cynthia'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Gay'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '130 Mason Farm Rd, CB #7030'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered 'Chapel Hill'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 23:05:35
Un-reviewed for Safety.	System	17 Nov 2020 13:56:04
DataPoint Un-verified.	System	17 Nov 2020 13:56:04
User entered empty.	System	17 Nov 2020 13:56:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:55:53
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
User entered 'North Carolina'	Mandy Tipton (b) (4)	12 Nov 2020 14:37:41
	(b) (4)	

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:37:13
User entered '27599-7030'	System	03 Nov 2020 20:35:35

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:30:08
User entered 'US'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:11:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Nov 2020 23:05:52
User entered '3'	System	17 Nov 2020 13:56:04
User entered '2'	System	12 Nov 2020 00:30:19
User entered '1'	System	03 Nov 2020 20:37:23

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:11:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '18/Nov/2020 18:05'	System	18 Nov 2020 23:05:52

US3692016

Folder: SAE USA-US123-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:11:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 23:05:52