

US3532192 (Prod: Children's Healthcare of Atlanta)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:37:08

All time stamps listed in this document are displayed in GMT

US3532192

Form: Participant Creation

Generated On: 26 Nov 2020 09:37:08

[Participant ID](#)

US3532192

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

US3532192

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

Date of Birth (MMM yyyy)	(b) (6) 1981
Age	38
Age Units	YEARS
Age (Derived)	38
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

US3532192

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:37:08

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3532192

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:37:08

Were any significant conditions reported?

Yes ☒

No ☐

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:08

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:22 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:22
Height (<i>xxx.x</i>)	185 cm
Weight (<i>xxx.x</i>)	82 kg
BMI (<i>xxx.x</i>)	23.95909 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)	

US3532192

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

(b) (6) FACILITY
MANAGEMENT

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

v6.020 DTW (1102)

15 of 1727

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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	

US3532192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:08

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

What was the participant's randomization number? 145425

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 ☒

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:08

Height	ND - Not Done
Weight	ND - Not Done

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	14:22 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:22
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	16:18 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 16:18
Temperature (xxx.x)	97.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	167 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3532192

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	31 AUG 2020
What was the treatment time? (00:00-23:59)	15:45 (24 HR)
Treatment Date and Time (derived)	31 AUG 2020 15:45
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

US3532192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

31 AUG 2020

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

15:33 (24 HR)

Collection date and time (derived)

31 AUG 2020 15:33

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:37:08

Collection date (<i>dd MMM yyyy</i>)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:20	31 AUG 2020 15:20
Nasopharyngeal Swab 2	No		

US3532192

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

97.2 °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

31 AUG 2020 16:22

PC Open Date & Time

31 AUG 2020 16:05

PC Close Date & Time

31 AUG 2020 18:35

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 05:36

PC Open Date & Time

31 AUG 2020 19:30

PC Close Date & Time

01 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 01:55

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 01:35

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 06:55

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 07:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 22:06

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

31 AUG 2020 16:23

PC Open Date & Time

31 AUG 2020 16:05

PC Close Date & Time

31 AUG 2020 18:35

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 05:38

PC Open Date & Time

31 AUG 2020 19:30

PC Close Date & Time

01 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

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

01 SEP 2020 23:18

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 01:36

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

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

03 SEP 2020 20:45

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 07:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

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

05 SEP 2020 22:06

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 16:24
PC Open Date & Time	31 AUG 2020 16:05
PC Close Date & Time	31 AUG 2020 18:35

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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

No ☐

Yes ☒

PC Time stamp	01 SEP 2020 05:39

PC Open Date & Time	31 AUG 2020 19:30

PC Close Date & Time	01 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

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 ☒

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

Yes ☐	
PC Time stamp	01 SEP 2020 23:19
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

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 ☒

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

Yes ☐	
PC Time stamp	03 SEP 2020 01:36
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

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 ☒

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

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 ☒

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

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 ☒

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

Yes ☐	
PC Time stamp	05 SEP 2020 22:06
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

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

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	6 OCT 2020
Time of assessment (00:00-23:59)	13:51 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 13:51
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	6 OCT 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 15:30
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3532192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

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

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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)	6 OCT 2020
What was the treatment time? (00:00-23:59)	15:00 (24 HR)
Treatment Date and Time (derived)	6 OCT 2020 15:00
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3532192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	6 OCT 2020
Collection time (<i>00:00-23:59</i>)	14:23 (24 HR)
Collection date and time (derived)	6 OCT 2020 14:23

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:37:08

Collection date (<i>dd MMM yyyy</i>)			6 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:55	6 OCT 2020 13:55
Nasopharyngeal Swab 2	No		

US3532192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 15:37

PC Open Date & Time

06 OCT 2020 15:20

PC Close Date & Time

06 OCT 2020 17:50

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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 97.4 °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	07 OCT 2020 01:53
PC Open Date & Time	06 OCT 2020 18:45
PC Close Date & Time	07 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

08 OCT 2020 00:05

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 05:50

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 01:42

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 06:02

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 07:47

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 22:33

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

06 OCT 2020 15:37

PC Open Date & Time

06 OCT 2020 15:20

PC Close Date & Time

06 OCT 2020 17:50

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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

07 OCT 2020 01:53

PC Open Date & Time

06 OCT 2020 18:45

PC Close Date & Time

07 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

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

08 OCT 2020 00:06

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

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

09 OCT 2020 05:50

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

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

10 OCT 2020 01:43

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

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

11 OCT 2020 05:59

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

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

12 OCT 2020 07:47

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

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

12 OCT 2020 22:33

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 15:38
PC Open Date & Time	06 OCT 2020 15:20
PC Close Date & Time	06 OCT 2020 17:50

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 01:55
PC Open Date & Time	06 OCT 2020 18:45
PC Close Date & Time	07 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

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 ☒

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

Yes ☐	
PC Time stamp	08 OCT 2020 00:10
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

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 ☒

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

Yes ☐	
PC Time stamp	09 OCT 2020 05:51
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

		Yes ☐
PC Time stamp	10 OCT 2020 01:43	
PC Open Date & Time	09 OCT 2020 12:00	
PC Close Date & Time	10 OCT 2020 11:59	

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

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 ☒

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

Yes ☐	
PC Time stamp	11 OCT 2020 05:59
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

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 ☒

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

Yes ☐	
PC Time stamp	12 OCT 2020 07:48
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

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 ☒

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

Yes ☐	
PC Time stamp	12 OCT 2020 22:33
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3532192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

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.

US3532192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	11 NOV 2020
Collection time (<i>00:00-23:59</i>)	15:19 (24 HR)
Collection date and time (derived)	11 NOV 2020 15:19

US3532192

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 11:20:55
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 01:43:23
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 02:32:27

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 FEB 2022 00:01

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27 FEB 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 MAR 2022 00:01

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27 MAR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 MAR 2022 00:01

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03 APR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JUL 2022 00:01

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17 JUL 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JUL 2022 00:01

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24 JUL 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 JUL 2022 00:01

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31 JUL 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 AUG 2022 00:01

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14 AUG 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 AUG 2022 00:01

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21 AUG 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3532192

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532192

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:37:08

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3532192

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:37:08

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

AEID	
Adverse event	NOSEBLEED
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)	19 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	20 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)

336 of 1727

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAS HISTORY OF NOSEBLEEDS SINCE 2014. HAS SEEN A DOCTOR FOR THEM IN THE PAST BUT NO KNOWN ETIOLOGY. NOT RELATED TO VACCINE, DUE TO PRIOR HISTORY
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)	

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

AEID	USA-US077-2020-MRNA-1273-P30 1000012
Adverse event	KIDNEY CANCER
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102) 338 of 1727

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

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	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	NEW DIAGNOSIS OF CANCER. AWAITING KIDNEY REMOVAL. DIAGNOSED WEHN HE WAS UNDERGOING WORKUP FOR KIDNEY TRANSPLANT. NOT RELATED TO VACCINE. HAD BASELINE KIDNEY FAILURE
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:37:08

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

Yes ☒

No ☐

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

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

Name of Medication	ISOSORBIDE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	90
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 ☐

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

Name of Medication	CARVEDILOL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

Name of Medication	AMLODIPINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
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 ☐

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	30
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 ☐

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

Name of Medication	POTASSIUM
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH
Dose per administration	10
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MEQ
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 ☐

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

Name of Medication	CALCIUM
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC KIDNEY FAILURE
Dose per administration	1334
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 ☐

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

Name of Medication	TUMS
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC KIDNEY FAILURE
Dose per administration	1000
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 ☐

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

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)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:37:08

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3532192

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:37:08

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

US3532192

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:37:08

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 ☐

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

SAEID	USA-US077-2020-MRNA-1273-P301000012
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:08

SAEID	USA-US077-2020-MRNA-1273-P301000012
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	13/NOV/2020 08:17
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

US3532192 (Prod: Children's Healthcare of Atlanta)

US3532192

Form: Participant Creation

Generated On: 26 Nov 2020 09:37:08

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3532192'	RWS_ENDPOINT ENDPOINT (b) (4) 	31 Aug 2020 18:19:45

US3532192

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:48:48

US3532192

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	31 Aug 2020 18:19:46

US3532192

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:48:48

US3532192

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	31 Aug 2020 18:48:48

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered (b) (6) 1981'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	31 Aug 2020 18:19:47

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[Age](#)

Audit	User	Time (GMT)
User entered '38'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '38'	System	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[White](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[Black](#)

Audit	User	Time (GMT)
User entered '1'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:08

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '2020'	System	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:08

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	31 Aug 2020 18:19:46

US3532192

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:37:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:07:46

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:20:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:20:42
Data point term sent to Coder	System	31 Aug 2020 20:09:14
User entered 'chronic kidney failure'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '2014'	System	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:08

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:18:15
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'was r/t kidney failure and no longer ongoing since dialysis, meds for kidney failure treated the heart failure' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:04:12
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:29:01
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 20:09:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 20:09:38
Data point term sent to Coder	System	31 Aug 2020 20:09:15
User entered 'congestive heart failure'	Peggy Kettle (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '2019'	System	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '2019'	System	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:08

[Condition](#)

Audit	User	Time (GMT)
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)	31 Aug 2020 20:11:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 20:11:45
Data point term sent to Coder	System	31 Aug 2020 20:10:15
User entered 'hypertension'	Peggy Kettle (b) (4)	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2014' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:33:17
User entered '31 Aug 2020'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	13 Oct 2020 16:33:17
User entered 'Aug 2020'	System	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '2014'	System	13 Oct 2020 16:33:17
User entered '2020'	System	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:08

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:09:45
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'MH 1' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:04:47
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:29:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Dialysis, LLT: Dialysis - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 20:11:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 20:11:45
Data point term sent to Coder	System	31 Aug 2020 20:10:17
User entered 'dialysis'	Peggy Kettle (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:36:27
Query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' answered with 'subject in on dialysis, continuing' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:05:16
User opened query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:29:31
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '2018'	System	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 00:26:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 00:26:37
Data point term sent to Coder	System	03 Sep 2020 00:25:47
Coding entries removed.	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:25:06
User entered 'HYPOKALEMIA' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:25:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Calcium metabolism disorders, PT: Hypocalcaemia, LLT: Hypocalcemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:11:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:11:44
Data point term sent to Coder	System	31 Aug 2020 20:10:18
User entered 'hypocalcemia'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '2018'	System	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Nosebleed - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 05:12:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 05:12:31
Data point term sent to Coder	System	20 Oct 2020 19:48:02
User entered 'Intermittent Nosebleeds'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '2014'	System	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '14:22'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 14:22'	System	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '185' cm	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14
DataPoint set to visible.	(b) (4) System	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 19:13:25
User entered '82' kg reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 19:13:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 19:13:14
User entered '82' (non-conformant).	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14
DataPoint set to visible.	System	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '23.95909'	System	31 Aug 2020 19:13:25
User entered empty.	System	31 Aug 2020 19:13:14
DataPoint set to visible.	System	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	31 Aug 2020 19:13:25
User entered empty.	System	31 Aug 2020 19:13:14
DataPoint set to visible.	System	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:36:21

US3532192

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 19:36:21

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:17
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:17
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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 closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:17
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:17
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:17
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:17
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:17
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:17
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:17
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:17
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:06:17
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

[Specify](#)

Audit	User	Time (GMT)
User entered (b) (6) facility management'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '1'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:08

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:02:57

US3532192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:02:57

US3532192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:02:57

US3532192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	31 Aug 2020 20:02:57

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	31 Aug 2020 19:14:38

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '145425'	RWS_ENDPOINT ENDPOINT (b) (4) 	31 Aug 2020 19:14:38

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) 	31 Aug 2020 19:14:38

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:08

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)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:03:09

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:03:09

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:03:09

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:03:09

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:08

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:03:09

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Etza Peters (b) (4)	25 Sep 2020 16:09:12
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 08:47:30
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:47:29

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:08

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:08

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:08

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:08

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '14:22'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 14:22'	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '20'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '141'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '82'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:08

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:08

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:42:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:42:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:31
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:04:01
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '16:18' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 16:18'	System	31 Aug 2020 20:42:31
User entered empty.	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 20:42:55
User entered '97.2' F reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:55
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:55
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 20:42:55
User entered '60' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:55
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 20:42:55
User entered empty.	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 20:42:55
User entered '16' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:55
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 20:42:55
User entered empty.	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 17:39:49
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Peggy Kettle (b) (4)	03 Sep 2020 00:21:17
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	31 Aug 2020 20:42:55
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	31 Aug 2020 20:42:55
User entered '167' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:55
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 20:42:55
User entered empty.	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 20:42:55
User entered '99' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:55
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 20:42:55
User entered empty.	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:10

US3532192

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:10

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '15:45'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 15:45'	System	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:05:01

US3532192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:05:01

US3532192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '15:33'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:05:01

US3532192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 15:33'	System	31 Aug 2020 20:05:01

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:37:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	31 Aug 2020 22:18:49
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	31 Aug 2020 22:18:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 22:18:49
User entered '15:20' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 22:18:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 20:05:23
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	31 Aug 2020 20:05:23
User entered '15:' (non-conformant).	Peggy Kettle (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 15:20'	System	31 Aug 2020 22:18:49
User entered '31 Aug 2020 15:' (non-conformant).	System	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:43:10

US3532192

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:43:10

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:22:02', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '1dd59f35-d46d-4afc-9156-31e7e682c78b'	System	31 Aug 2020 20:25:20
User entered 'Yes (Y)'	System	31 Aug 2020 20:25:20

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:22:08', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '1dd59f35-d46d-4afc-9156-31e7e682c78b'	System	31 Aug 2020 20:25:20
User entered '97.2'	System	31 Aug 2020 20:25:20

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:22:14', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '1dd59f35-d46d-4afc-9156-31e7e682c78b'	System	31 Aug 2020 20:25:20
User entered 'No (N)'	System	31 Aug 2020 20:25:20

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:22:27', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '1dd59f35-d46d-4afc-9156-31e7e682c78b'	System	31 Aug 2020 20:25:20
User entered '31 Aug 2020 16:22'	System	31 Aug 2020 20:25:20

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 16:05'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 18:35'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:35:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ff7f0a29-733c-41f6-b927-105215afb855'	System	01 Sep 2020 09:36:18
User entered 'Yes (Y)'	System	01 Sep 2020 09:36:18

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:35:59', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ff7f0a29-733c-41f6-b927-105215afb855'	System	01 Sep 2020 09:36:18
User entered '98.1'	System	01 Sep 2020 09:36:18

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:36:09', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ff7f0a29-733c-41f6-b927-105215afb855'	System	01 Sep 2020 09:36:18
User entered 'No (N)'	System	01 Sep 2020 09:36:18

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:36:17', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ff7f0a29-733c-41f6-b927-105215afb855'	System	01 Sep 2020 09:36:18
User entered '01 Sep 2020 05:36'	System	01 Sep 2020 09:36:18

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 19:30'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 2'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-02T01:55:22', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fefa07ec-d79a-49ff-86eb-e5056bd0f60b'	System	02 Sep 2020 05:55:35
User entered 'Yes (Y)'	System	02 Sep 2020 05:55:35

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-02T01:55:25', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fefa07ec-d79a-49ff-86eb-e5056bd0f60b' User entered '97.7'	System	02 Sep 2020 05:55:35
	System	02 Sep 2020 05:55:35

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-02T01:55:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fefa07ec-d79a-49ff-86eb-e5056bd0f60b'	System	02 Sep 2020 05:55:35
User entered 'No (N)'	System	02 Sep 2020 05:55:35

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-02T01:55:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fefa07ec-d79a-49ff-86eb-e5056bd0f60b'	System	02 Sep 2020 05:55:35
User entered '02 Sep 2020 01:55'	System	02 Sep 2020 05:55:35

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 3'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:32', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '20639c4d-e9f4-4aaa-a3c5-8f16e0c10643'	System	03 Sep 2020 05:35:46
User entered 'Yes (Y)'	System	03 Sep 2020 05:35:46

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '20639c4d-e9f4-4aaa-a3c5-8f16e0c10643'	System	03 Sep 2020 05:35:46
User entered '97.7'	System	03 Sep 2020 05:35:46

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:40', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '20639c4d-e9f4-4aaa-a3c5-8f16e0c10643'	System	03 Sep 2020 05:35:46
User entered 'No (N)'	System	03 Sep 2020 05:35:46

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '20639c4d-e9f4-4aaa-a3c5-8f16e0c10643'	System	03 Sep 2020 05:35:46
User entered '03 Sep 2020 01:35'	System	03 Sep 2020 05:35:46

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 4'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-04T06:55:22', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '777f97fd-c7da-4548-b3f8-483d354a138b'	System	04 Sep 2020 10:55:39
User entered 'Yes (Y)'	System	04 Sep 2020 10:55:39

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-04T06:55:27', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '777f97fd-c7da-4548-b3f8-483d354a138b'	System	04 Sep 2020 10:55:39
User entered '97.4'	System	04 Sep 2020 10:55:39

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-04T06:55:34', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '777f97fd-c7da-4548-b3f8-483d354a138b'	System	04 Sep 2020 10:55:39
User entered 'No (N)'	System	04 Sep 2020 10:55:39

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-04T06:55:37', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '777f97fd-c7da-4548-b3f8-483d354a138b'	System	04 Sep 2020 10:55:39
User entered '04 Sep 2020 06:55'	System	04 Sep 2020 10:55:39

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 5'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '24ec0331-ed3-46fd-be0e-17a430839170'	System	05 Sep 2020 11:05:40
User entered 'Yes (Y)'	System	05 Sep 2020 11:05:40

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '24ec0331-ed3-46fd-be0e-17a430839170'	System	05 Sep 2020 11:05:40
User entered '96.7'	System	05 Sep 2020 11:05:40

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '24ec0331-ed3-46fd-be0e-17a430839170'	System	05 Sep 2020 11:05:40
User entered 'No (N)'	System	05 Sep 2020 11:05:40

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:37', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '24ec0331-ed3-46fd-be0e-17a430839170'	System	05 Sep 2020 11:05:40
User entered '05 Sep 2020 07:05'	System	05 Sep 2020 11:05:40

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 6'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:11', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'a8d3491b-52c0-4253-a831-abcbeba25ff7'	System	06 Sep 2020 02:06:22
User entered 'Yes (Y)'	System	06 Sep 2020 02:06:22

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:14', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'a8d3491b-52c0-4253-a831-abcbeba25ff7'	System	06 Sep 2020 02:06:22
User entered '97.7'	System	06 Sep 2020 02:06:22

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:17', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'a8d3491b-52c0-4253-a831-abcbeba25ff7'	System	06 Sep 2020 02:06:22
User entered 'No (N)'	System	06 Sep 2020 02:06:22

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:20', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'a8d3491b-52c0-4253-a831-abcbeba25ff7'	System	06 Sep 2020 02:06:22
User entered '05 Sep 2020 22:06'	System	06 Sep 2020 02:06:22

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 7'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:22:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5a924a97-cde4-4374-9f10-a9f1525e0040'	System	31 Aug 2020 20:26:32
User entered 'None (1)'	System	31 Aug 2020 20:26:32

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5a924a97-cde4-4374-9f10-a9f1525e0040'	System	31 Aug 2020 20:26:32
User entered 'No (N)'	System	31 Aug 2020 20:26:32

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:07', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5a924a97-cde4-4374-9f10-a9f1525e0040'	System	31 Aug 2020 20:26:32
User entered 'No (N)'	System	31 Aug 2020 20:26:32

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5a924a97-cde4-4374-9f10-a9f1525e0040'	System	31 Aug 2020 20:26:32
User entered 'None (1)'	System	31 Aug 2020 20:26:32

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5a924a97-cde4-4374-9f10-a9f1525e0040'	System	31 Aug 2020 20:26:32
User entered '31 Aug 2020 16:23'	System	31 Aug 2020 20:26:32

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 16:05'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 18:35'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:37:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fdf1e3aa-5241-46f4-b134-9753d80e2e9b'	System	01 Sep 2020 09:38:18
User entered 'None (1)'	System	01 Sep 2020 09:38:18

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:37:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fdf1e3aa-5241-46f4-b134-9753d80e2e9b'	System	01 Sep 2020 09:38:18
User entered 'No (N)'	System	01 Sep 2020 09:38:18

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:37:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fdf1e3aa-5241-46f4-b134-9753d80e2e9b'	System	01 Sep 2020 09:38:18
User entered 'No (N)'	System	01 Sep 2020 09:38:18

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:38:11', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fdf1e3aa-5241-46f4-b134-9753d80e2e9b'	System	01 Sep 2020 09:38:18
User entered 'None (1)'	System	01 Sep 2020 09:38:18

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:38:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fdf1e3aa-5241-46f4-b134-9753d80e2e9b'	System	01 Sep 2020 09:38:18
User entered '01 Sep 2020 05:38'	System	01 Sep 2020 09:38:18

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 19:30'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 2'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0a9dea41-2d94-4758-b8e2-466d350be327'	System	02 Sep 2020 03:18:38
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 03:18:38

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:07', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0a9dea41-2d94-4758-b8e2-466d350be327'	System	02 Sep 2020 03:18:38
User entered 'No (N)'	System	02 Sep 2020 03:18:38

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:22', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0a9dea41-2d94-4758-b8e2-466d350be327'	System	02 Sep 2020 03:18:38
User entered 'No (N)'	System	02 Sep 2020 03:18:38

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:31', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0a9dea41-2d94-4758-b8e2-466d350be327'	System	02 Sep 2020 03:18:38
User entered 'None (1)'	System	02 Sep 2020 03:18:38

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:34', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0a9dea41-2d94-4758-b8e2-466d350be327'	System	02 Sep 2020 03:18:38
User entered '01 Sep 2020 23:18'	System	02 Sep 2020 03:18:38

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 3'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:13', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b4ea75f3-5bab-45bb-88bd-f85a34467db9'	System	03 Sep 2020 05:36:30
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 05:36:30

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:16', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b4ea75f3-5bab-45bb-88bd-f85a34467db9'	System	03 Sep 2020 05:36:30
User entered 'No (N)'	System	03 Sep 2020 05:36:30

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:21', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b4ea75f3-5bab-45bb-88bd-f85a34467db9'	System	03 Sep 2020 05:36:30
User entered 'No (N)'	System	03 Sep 2020 05:36:30

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b4ea75f3-5bab-45bb-88bd-f85a34467db9'	System	03 Sep 2020 05:36:30
User entered 'None (1)'	System	03 Sep 2020 05:36:30

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b4ea75f3-5bab-45bb-88bd-f85a34467db9' User entered '03 Sep 2020 01:36'	System	03 Sep 2020 05:36:30
	System	03 Sep 2020 05:36:30

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 4'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cc147048-95fb-412b-aa9a-4ea82e2d18d5'	System	04 Sep 2020 10:55:21
User entered 'None (1)'	System	04 Sep 2020 10:55:21

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:21', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cc147048-95fb-412b-aa9a-4ea82e2d18d5'	System	04 Sep 2020 10:55:21
User entered 'No (N)'	System	04 Sep 2020 10:55:21

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cc147048-95fb-412b-aa9a-4ea82e2d18d5'	System	04 Sep 2020 10:55:21
User entered 'No (N)'	System	04 Sep 2020 10:55:21

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:29', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cc147048-95fb-412b-aa9a-4ea82e2d18d5'	System	04 Sep 2020 10:55:21
User entered 'None (1)'	System	04 Sep 2020 10:55:21

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:31', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cc147048-95fb-412b-aa9a-4ea82e2d18d5'	System	04 Sep 2020 10:55:21
User entered '03 Sep 2020 20:45'	System	04 Sep 2020 10:55:21

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 5'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e21d2f3-c9cd-4e41-b58d-b4c9a7b0cbe8'	System	05 Sep 2020 11:05:20
User entered 'None (1)'	System	05 Sep 2020 11:05:20

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e21d2f3-c9cd-4e41-b58d-b4c9a7b0cbe8'	System	05 Sep 2020 11:05:20
User entered 'No (N)'	System	05 Sep 2020 11:05:20

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:09', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e21d2f3-c9cd-4e41-b58d-b4c9a7b0cbe8'	System	05 Sep 2020 11:05:20
User entered 'No (N)'	System	05 Sep 2020 11:05:20

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:13', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e21d2f3-c9cd-4e41-b58d-b4c9a7b0cbe8'	System	05 Sep 2020 11:05:20
User entered 'None (1)'	System	05 Sep 2020 11:05:20

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:16', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e21d2f3-c9cd-4e41-b58d-b4c9a7b0cbe8'	System	05 Sep 2020 11:05:20
User entered '05 Sep 2020 07:05'	System	05 Sep 2020 11:05:20

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 6'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '946b2bb4-727e-4f50-bba5-f196fb594482'	System	06 Sep 2020 02:06:55
User entered 'None (1)'	System	06 Sep 2020 02:06:55

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:45', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '946b2bb4-727e-4f50-bba5-f196fb594482'	System	06 Sep 2020 02:06:55
User entered 'No (N)'	System	06 Sep 2020 02:06:55

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '946b2bb4-727e-4f50-bba5-f196fb594482'	System	06 Sep 2020 02:06:55
User entered 'No (N)'	System	06 Sep 2020 02:06:55

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '946b2bb4-727e-4f50-bba5-f196fb594482'	System	06 Sep 2020 02:06:55
User entered 'None (1)'	System	06 Sep 2020 02:06:55

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:54', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '946b2bb4-727e-4f50-bba5-f196fb594482'	System	06 Sep 2020 02:06:55
User entered '05 Sep 2020 22:06'	System	06 Sep 2020 02:06:55

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 7'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66'	System	31 Aug 2020 20:27:01
User entered 'None (0)'	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:40', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66'	System	31 Aug 2020 20:27:01
User entered 'None (0)'	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:44', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66'	System	31 Aug 2020 20:27:01
User entered 'None (0)'	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:47', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66'	System	31 Aug 2020 20:27:01
User entered 'None (0)'	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66'	System	31 Aug 2020 20:27:01
User entered 'None (0)'	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:54', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66'	System	31 Aug 2020 20:27:01
User entered 'None (0)'	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:24:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66'	System	31 Aug 2020 20:27:01
User entered 'No (N)'	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:24:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66'	System	31 Aug 2020 20:27:01
User entered '31 Aug 2020 16:24'	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 16:05'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 18:35'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:38:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7'	System	01 Sep 2020 09:39:19
User entered 'None (0)'	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:38:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7'	System	01 Sep 2020 09:39:19
User entered 'None (0)'	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:38:57', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7'	System	01 Sep 2020 09:39:19
User entered 'None (0)'	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:39:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7'	System	01 Sep 2020 09:39:19
User entered 'None (0)'	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:39:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7'	System	01 Sep 2020 09:39:19
User entered 'None (0)'	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:39:07', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7'	System	01 Sep 2020 09:39:19
User entered 'None (0)'	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:39:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7'	System	01 Sep 2020 09:39:19
User entered 'Yes (Y)'	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:39:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7'	System	01 Sep 2020 09:39:19
User entered '01 Sep 2020 05:39'	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 19:30'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 2'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:44', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f'	System	02 Sep 2020 03:19:49
User entered 'None (0)'	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:56', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f'	System	02 Sep 2020 03:19:49
User entered 'None (0)'	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:20', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f'	System	02 Sep 2020 03:19:49
User entered 'None (0)'	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f'	System	02 Sep 2020 03:19:49
User entered 'None (0)'	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:28', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f'	System	02 Sep 2020 03:19:49
User entered 'None (0)'	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:32', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f'	System	02 Sep 2020 03:19:49
User entered 'None (0)'	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f'	System	02 Sep 2020 03:19:49
User entered 'No (N)'	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:45', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f'	System	02 Sep 2020 03:19:49
User entered '01 Sep 2020 23:19'	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 3'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:49', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741'	System	03 Sep 2020 05:36:08
User entered 'None (0)'	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:51', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741'	System	03 Sep 2020 05:36:08
User entered 'None (0)'	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741'	System	03 Sep 2020 05:36:08
User entered 'None (0)'	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:55', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741'	System	03 Sep 2020 05:36:08
User entered 'None (0)'	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741'	System	03 Sep 2020 05:36:08
User entered 'None (0)'	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741'	System	03 Sep 2020 05:36:08
User entered 'None (0)'	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:05', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741'	System	03 Sep 2020 05:36:08
User entered 'No (N)'	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741'	System	03 Sep 2020 05:36:08
User entered '03 Sep 2020 01:36'	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 4'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:39', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12'	System	04 Sep 2020 00:45:07
User entered 'None (0)'	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:41', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12'	System	04 Sep 2020 00:45:07
User entered 'None (0)'	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:44', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12'	System	04 Sep 2020 00:45:07
User entered 'None (0)'	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:47', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12'	System	04 Sep 2020 00:45:07
User entered 'None (0)'	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:51', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12'	System	04 Sep 2020 00:45:07
User entered 'None (0)'	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12'	System	04 Sep 2020 00:45:07
User entered 'None (0)'	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12'	System	04 Sep 2020 00:45:07
User entered 'No (N)'	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12'	System	04 Sep 2020 00:45:07
User entered '03 Sep 2020 20:45'	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 5'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:51:59', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c'	System	05 Sep 2020 11:04:53
User entered 'None (0)'	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:52:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c'	System	05 Sep 2020 11:04:53
User entered 'None (0)'	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:52:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c'	System	05 Sep 2020 11:04:53
User entered 'None (0)'	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:52:29', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c'	System	05 Sep 2020 11:04:53
User entered 'None (0)'	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:52:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c'	System	05 Sep 2020 11:04:53
User entered 'None (0)'	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:52:41', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c'	System	05 Sep 2020 11:04:53
User entered 'None (0)'	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:04:49', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c'	System	05 Sep 2020 11:04:53
User entered 'No (N)'	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:04:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c'	System	05 Sep 2020 11:04:53
User entered '05 Sep 2020 07:04'	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 6'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:23', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b'	System	06 Sep 2020 02:06:40
User entered 'None (0)'	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b'	System	06 Sep 2020 02:06:40
User entered 'None (0)'	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:27', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b'	System	06 Sep 2020 02:06:40
User entered 'None (0)'	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:29', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b'	System	06 Sep 2020 02:06:40
User entered 'None (0)'	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:31', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b'	System	06 Sep 2020 02:06:40
User entered 'None (0)'	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b'	System	06 Sep 2020 02:06:40
User entered 'None (0)'	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:36', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b'	System	06 Sep 2020 02:06:40
User entered 'No (N)'	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:38', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b'	System	06 Sep 2020 02:06:40
User entered '05 Sep 2020 22:06'	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 7'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:34

US3532192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:34

US3532192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:34

US3532192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:34

US3532192

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:38

US3532192

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 13:37:38

US3532192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:48

US3532192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:48

US3532192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:48

US3532192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:48

US3532192

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:52

US3532192

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 13:37:52

US3532192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	21 Sep 2020 13:37:42

US3532192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Peggy Kettle (b) (4) (b) (4)	21 Sep 2020 13:37:42

US3532192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Peggy Kettle (b) (4) (b) (4)	21 Sep 2020 13:37:42

US3532192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	21 Sep 2020 13:37:42

US3532192

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	21 Sep 2020 13:37:47

US3532192

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 13:37:47

US3532192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:16:17

US3532192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 11:17:51
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'confirm' (Site from System).	Etza Peters (b) (4)	06 Oct 2020 19:33:05
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	06 Oct 2020 19:16:17
User entered '6 Oct 2020'	Etza Peters (b) (4)	06 Oct 2020 19:16:17

US3532192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:16:17

US3532192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	06 Oct 2020 19:16:17

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '13:51'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '6 Oct 2020 13:51'	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.6' F	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '18'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '156'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '89'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 19:54:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 19:54:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 19:21:48
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '15:30' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '6 Oct 2020 15:30'	System	06 Oct 2020 19:54:51
User entered empty.	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Post-dose vitals signs is required per protocol. Please clarify why pulse rate was not done' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:54:56
Query 'Per CDM: Post-dose vitals signs is required per protocol. Please clarify why pulse rate was not done' answered with 'blood pressure machine was acting up and had to take BP manually. Staff forgot to measure HR.' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	28 Oct 2020 16:39:16
User opened query 'Per CDM: Post-dose vitals signs is required per protocol. Please clarify why pulse rate was not done' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:35:55
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 16:41:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 16:41:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:41:32
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 16:41:32
User entered empty.	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '20' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Oct 2020 19:54:51
User entered empty.	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '130' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 19:54:51
User entered empty.	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '70' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 19:54:51
User entered empty.	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:56

US3532192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:56

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '15:00'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '6 Oct 2020 15:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:22:53

US3532192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:22:53

US3532192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '14:23'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:22:53

US3532192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '6 Oct 2020 14:23'	System	06 Oct 2020 19:22:53

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Etza Peters (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '13:55'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '6 Oct 2020 13:55'	System	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Etza Peters (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:36:35

US3532192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 19:36:35

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:36:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '61270d7c-285c-473e-94db-4712ad14f249'	System	06 Oct 2020 19:37:23
User entered 'Yes (Y)'	System	06 Oct 2020 19:37:23

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:36:54', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '61270d7c-285c-473e-94db-4712ad14f249'	System	06 Oct 2020 19:37:23
User entered '97.6'	System	06 Oct 2020 19:37:23

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:36:59', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '61270d7c-285c-473e-94db-4712ad14f249'	System	06 Oct 2020 19:37:23
User entered 'No (N)'	System	06 Oct 2020 19:37:23

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '61270d7c-285c-473e-94db-4712ad14f249'	System	06 Oct 2020 19:37:23
User entered '06 Oct 2020 15:37'	System	06 Oct 2020 19:37:23

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 15:20'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 17:50'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:08', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'c8af0c4b-9ad1-4eb4-9669-b5ab6ea9721a'	System	07 Oct 2020 05:53:22
User entered 'Yes (Y)'	System	07 Oct 2020 05:53:22

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:12', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'c8af0c4b-9ad1-4eb4-9669-b5ab6ea9721a' User entered '97.4'	System	07 Oct 2020 05:53:22

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:17', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'c8af0c4b-9ad1-4eb4-9669-b5ab6ea9721a'	System	07 Oct 2020 05:53:22
User entered 'No (N)'	System	07 Oct 2020 05:53:22

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:20', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'c8af0c4b-9ad1-4eb4-9669-b5ab6ea9721a' User entered '07 Oct 2020 01:53'	System	07 Oct 2020 05:53:22
	System	07 Oct 2020 05:53:22

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 18:45'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 2'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:04:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ed0d5b8e-875b-4780-a0aa-e244b365e6c5'	System	08 Oct 2020 04:05:50
User entered 'Yes (Y)'	System	08 Oct 2020 04:05:50

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:05:02', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ed0d5b8e-875b-4780-a0aa-e244b365e6c5'	System	08 Oct 2020 04:05:50
User entered '98.0'	System	08 Oct 2020 04:05:50

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:05:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ed0d5b8e-875b-4780-a0aa-e244b365e6c5'	System	08 Oct 2020 04:05:50
User entered 'No (N)'	System	08 Oct 2020 04:05:50

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:05:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ed0d5b8e-875b-4780-a0aa-e244b365e6c5'	System	08 Oct 2020 04:05:50
User entered '08 Oct 2020 00:05'	System	08 Oct 2020 04:05:50

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 3'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0ff37d08-1bb1-409c-a589-cbcbbae5b910'	System	09 Oct 2020 09:50:17
User entered 'Yes (Y)'	System	09 Oct 2020 09:50:17

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:08', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0ff37d08-1bb1-409c-a589-cbcbbae5b910'	System	09 Oct 2020 09:50:17
User entered '96.8'	System	09 Oct 2020 09:50:17

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:12', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0ff37d08-1bb1-409c-a589-cbcbbae5b910'	System	09 Oct 2020 09:50:17
User entered 'No (N)'	System	09 Oct 2020 09:50:17

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0ff37d08-1bb1-409c-a589-cbcbbae5b910'	System	09 Oct 2020 09:50:17
User entered '09 Oct 2020 05:50'	System	09 Oct 2020 09:50:17

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 4'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:42:38', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '995cafd9-6b1f-4673-931f-ab3d1b62ee48'	System	10 Oct 2020 05:42:54
User entered 'Yes (Y)'	System	10 Oct 2020 05:42:54

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:42:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '995cafd9-6b1f-4673-931f-ab3d1b62ee48'	System	10 Oct 2020 05:42:54
User entered '97.6'	System	10 Oct 2020 05:42:54

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:42:45', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '995cafd9-6b1f-4673-931f-ab3d1b62ee48'	System	10 Oct 2020 05:42:54
User entered 'No (N)'	System	10 Oct 2020 05:42:54

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:42:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '995cafd9-6b1f-4673-931f-ab3d1b62ee48'	System	10 Oct 2020 05:42:54
User entered '10 Oct 2020 01:42'	System	10 Oct 2020 05:42:54

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 5'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:57', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '8f3eaba2-4c02-40ff-b521-34fa2d27862a'	System	11 Oct 2020 10:02:12
User entered 'Yes (Y)'	System	11 Oct 2020 10:02:12

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T06:02:02', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '8f3eaba2-4c02-40ff-b521-34fa2d27862a' User entered '97.8'	System	11 Oct 2020 10:02:12

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T06:02:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '8f3eaba2-4c02-40ff-b521-34fa2d27862a'	System	11 Oct 2020 10:02:12
User entered 'No (N)'	System	11 Oct 2020 10:02:12

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T06:02:09', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '8f3eaba2-4c02-40ff-b521-34fa2d27862a' User entered '11 Oct 2020 06:02'	System	11 Oct 2020 10:02:12
	System	11 Oct 2020 10:02:12

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 6'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:46:28', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'f28a18f1-3447-4567-b153-f8440d031361'	System	12 Oct 2020 11:47:35
User entered 'Yes (Y)'	System	12 Oct 2020 11:47:35

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:25', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'f28a18f1-3447-4567-b153-f8440d031361'	System	12 Oct 2020 11:47:35
User entered '98.1'	System	12 Oct 2020 11:47:35

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:29', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'f28a18f1-3447-4567-b153-f8440d031361'	System	12 Oct 2020 11:47:35
User entered 'No (N)'	System	12 Oct 2020 11:47:35

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:32', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'f28a18f1-3447-4567-b153-f8440d031361'	System	12 Oct 2020 11:47:35
User entered '12 Oct 2020 07:47'	System	12 Oct 2020 11:47:35

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 7'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4311ab32-c308-4e1f-9139-5f3b2ad7be93'	System	13 Oct 2020 02:33:43
User entered 'Yes (Y)'	System	13 Oct 2020 02:33:43

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4311ab32-c308-4e1f-9139-5f3b2ad7be93'	System	13 Oct 2020 02:33:43
User entered '97.5'	System	13 Oct 2020 02:33:43

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:36', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4311ab32-c308-4e1f-9139-5f3b2ad7be93'	System	13 Oct 2020 02:33:43
User entered 'No (N)'	System	13 Oct 2020 02:33:43

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:38', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4311ab32-c308-4e1f-9139-5f3b2ad7be93'	System	13 Oct 2020 02:33:43
User entered '12 Oct 2020 22:33'	System	13 Oct 2020 02:33:43

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:14', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5741f0b8-e306-4af3-9262-538bce66210a' User entered 'None (1)'	System	06 Oct 2020 19:37:38
	System	06 Oct 2020 19:37:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5741f0b8-e306-4af3-9262-538bce66210a' User entered 'No (N)'	System	06 Oct 2020 19:37:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:31', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5741f0b8-e306-4af3-9262-538bce66210a' User entered 'No (N)'	System	06 Oct 2020 19:37:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5741f0b8-e306-4af3-9262-538bce66210a' User entered 'None (1)'	System	06 Oct 2020 19:37:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5741f0b8-e306-4af3-9262-538bce66210a' User entered '06 Oct 2020 15:37'	System	06 Oct 2020 19:37:38
	System	06 Oct 2020 19:37:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 15:20'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 17:50'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:34', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '89d7a545-197f-44b8-b108-bd37a9e70196'	System	07 Oct 2020 05:53:52
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 05:53:52

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:38', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '89d7a545-197f-44b8-b108-bd37a9e70196'	System	07 Oct 2020 05:53:52
User entered 'No (N)'	System	07 Oct 2020 05:53:52

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:43', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '89d7a545-197f-44b8-b108-bd37a9e70196'	System	07 Oct 2020 05:53:52
User entered 'No (N)'	System	07 Oct 2020 05:53:52

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:47', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '89d7a545-197f-44b8-b108-bd37a9e70196'	System	07 Oct 2020 05:53:52
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 05:53:52

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '89d7a545-197f-44b8-b108-bd37a9e70196'	System	07 Oct 2020 05:53:52
User entered '07 Oct 2020 01:53'	System	07 Oct 2020 05:53:52

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 18:45'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 2'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:05:55', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9b820423-c5ce-4369-ba68-0a5176e3a2ef'	System	08 Oct 2020 04:06:24
User entered 'None (1)'	System	08 Oct 2020 04:06:24

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:05:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9b820423-c5ce-4369-ba68-0a5176e3a2ef'	System	08 Oct 2020 04:06:24
User entered 'No (N)'	System	08 Oct 2020 04:06:24

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:06:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9b820423-c5ce-4369-ba68-0a5176e3a2ef'	System	08 Oct 2020 04:06:24
User entered 'No (N)'	System	08 Oct 2020 04:06:24

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:06:09', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9b820423-c5ce-4369-ba68-0a5176e3a2ef'	System	08 Oct 2020 04:06:24
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 04:06:24

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:06:21', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9b820423-c5ce-4369-ba68-0a5176e3a2ef' User entered '08 Oct 2020 00:06'	System	08 Oct 2020 04:06:24
	System	08 Oct 2020 04:06:24

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 3'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:19', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '26da0cd0-42c4-4cc5-a838-23a96975059a'	System	09 Oct 2020 09:50:38
User entered 'None (1)'	System	09 Oct 2020 09:50:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '26da0cd0-42c4-4cc5-a838-23a96975059a'	System	09 Oct 2020 09:50:38
User entered 'No (N)'	System	09 Oct 2020 09:50:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '26da0cd0-42c4-4cc5-a838-23a96975059a'	System	09 Oct 2020 09:50:38
User entered 'No (N)'	System	09 Oct 2020 09:50:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '26da0cd0-42c4-4cc5-a838-23a96975059a'	System	09 Oct 2020 09:50:38
User entered 'None (1)'	System	09 Oct 2020 09:50:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:36', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '26da0cd0-42c4-4cc5-a838-23a96975059a' User entered '09 Oct 2020 05:50'	System	09 Oct 2020 09:50:38
	System	09 Oct 2020 09:50:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 4'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:42:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fb2524bf-85e8-4689-aa3f-91515466612d'	System	10 Oct 2020 05:43:10
User entered 'None (1)'	System	10 Oct 2020 05:43:10

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fb2524bf-85e8-4689-aa3f-91515466612d'	System	10 Oct 2020 05:43:10
User entered 'No (N)'	System	10 Oct 2020 05:43:10

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fb2524bf-85e8-4689-aa3f-91515466612d'	System	10 Oct 2020 05:43:10
User entered 'No (N)'	System	10 Oct 2020 05:43:10

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fb2524bf-85e8-4689-aa3f-91515466612d'	System	10 Oct 2020 05:43:10
User entered 'None (1)'	System	10 Oct 2020 05:43:10

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:08', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fb2524bf-85e8-4689-aa3f-91515466612d'	System	10 Oct 2020 05:43:10
User entered '10 Oct 2020 01:43'	System	10 Oct 2020 05:43:10

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 5'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:38', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7fd4ff51-4141-431b-aecd-ac7ad9370a6a'	System	11 Oct 2020 09:59:54
User entered 'None (1)'	System	11 Oct 2020 09:59:54

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:43', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7fd4ff51-4141-431b-aecd-ac7ad9370a6a'	System	11 Oct 2020 09:59:54
User entered 'No (N)'	System	11 Oct 2020 09:59:54

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:46', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7fd4ff51-4141-431b-aecd-ac7ad9370a6a'	System	11 Oct 2020 09:59:54
User entered 'No (N)'	System	11 Oct 2020 09:59:54

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7fd4ff51-4141-431b-aecd-ac7ad9370a6a'	System	11 Oct 2020 09:59:54
User entered 'None (1)'	System	11 Oct 2020 09:59:54

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7fd4ff51-4141-431b-aecd-ac7ad9370a6a' User entered '11 Oct 2020 05:59'	System	11 Oct 2020 09:59:54
	System	11 Oct 2020 09:59:54

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 6'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:39', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ad4744fe-3104-4637-ab18-b85da448087b' User entered 'None (1)'	System	12 Oct 2020 11:47:56
	System	12 Oct 2020 11:47:56

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ad4744fe-3104-4637-ab18-b85da448087b'	System	12 Oct 2020 11:47:56
User entered 'No (N)'	System	12 Oct 2020 11:47:56

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:51', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ad4744fe-3104-4637-ab18-b85da448087b'	System	12 Oct 2020 11:47:56
User entered 'No (N)'	System	12 Oct 2020 11:47:56

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ad4744fe-3104-4637-ab18-b85da448087b'	System	12 Oct 2020 11:47:56
User entered 'None (1)'	System	12 Oct 2020 11:47:56

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:55', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ad4744fe-3104-4637-ab18-b85da448087b' User entered '12 Oct 2020 07:47'	System	12 Oct 2020 11:47:56
	System	12 Oct 2020 11:47:56

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 7'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:16', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '22e49dc3-2ac2-4372-a464-6bd1747672fa'	System	13 Oct 2020 02:33:28
User entered 'None (1)'	System	13 Oct 2020 02:33:28

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '22e49dc3-2ac2-4372-a464-6bd1747672fa'	System	13 Oct 2020 02:33:28
User entered 'No (N)'	System	13 Oct 2020 02:33:28

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:21', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '22e49dc3-2ac2-4372-a464-6bd1747672fa'	System	13 Oct 2020 02:33:28
User entered 'No (N)'	System	13 Oct 2020 02:33:28

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:23', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '22e49dc3-2ac2-4372-a464-6bd1747672fa'	System	13 Oct 2020 02:33:28
User entered 'None (1)'	System	13 Oct 2020 02:33:28

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:25', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '22e49dc3-2ac2-4372-a464-6bd1747672fa' User entered '12 Oct 2020 22:33'	System	13 Oct 2020 02:33:28
	System	13 Oct 2020 02:33:28

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:41', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf'	System	06 Oct 2020 19:38:08
User entered 'None (0)'	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:45', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf' User entered 'None (0)'	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:49', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf'	System	06 Oct 2020 19:38:08
User entered 'None (0)'	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:51', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf' User entered 'None (0)'	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf'	System	06 Oct 2020 19:38:08
User entered 'None (0)'	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:56', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf'	System	06 Oct 2020 19:38:08
User entered 'None (0)'	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:38:02', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf'	System	06 Oct 2020 19:38:08
User entered 'No (N)'	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:38:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf' User entered '06 Oct 2020 15:38'	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 15:20'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 17:50'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:22', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507'	System	07 Oct 2020 05:55:09
User entered 'None (0)'	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:29', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507'	System	07 Oct 2020 05:55:09
User entered 'No interference with activity (1)'	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507'	System	07 Oct 2020 05:55:09
User entered 'No interference with activity (1)'	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:43', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507'	System	07 Oct 2020 05:55:09
User entered 'None (0)'	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507'	System	07 Oct 2020 05:55:09
User entered 'None (0)'	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:57', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507'	System	07 Oct 2020 05:55:09
User entered 'No interference with activity (1)'	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:55:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507'	System	07 Oct 2020 05:55:09
User entered 'No (N)'	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:55:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507'	System	07 Oct 2020 05:55:09
User entered '07 Oct 2020 01:55'	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 18:45'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 2'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:09:41', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7'	System	08 Oct 2020 04:10:10
User entered 'None (0)'	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:09:46', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7'	System	08 Oct 2020 04:10:10
User entered 'No interference with activity (1)'	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:09:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7'	System	08 Oct 2020 04:10:10
User entered 'None (0)'	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:09:54', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7'	System	08 Oct 2020 04:10:10
User entered 'None (0)'	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:09:57', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7'	System	08 Oct 2020 04:10:10
User entered 'None (0)'	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:10:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7'	System	08 Oct 2020 04:10:10
User entered 'None (0)'	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:10:05', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7'	System	08 Oct 2020 04:10:10
User entered 'No (N)'	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:10:07', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7'	System	08 Oct 2020 04:10:10
User entered '08 Oct 2020 00:10'	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 3'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:40', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815'	System	09 Oct 2020 09:51:19
User entered 'None (0)'	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:44', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815'	System	09 Oct 2020 09:51:19
User entered 'None (0)'	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815'	System	09 Oct 2020 09:51:19
User entered 'None (0)'	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:56', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815'	System	09 Oct 2020 09:51:19
User entered 'None (0)'	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:51:05', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815'	System	09 Oct 2020 09:51:19
User entered 'None (0)'	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:51:08', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815'	System	09 Oct 2020 09:51:19
User entered 'None (0)'	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:51:12', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815'	System	09 Oct 2020 09:51:19
User entered 'No (N)'	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:51:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815'	System	09 Oct 2020 09:51:19
User entered '09 Oct 2020 05:51'	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 4'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:12', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa'	System	10 Oct 2020 05:43:34
User entered 'None (0)'	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa'	System	10 Oct 2020 05:43:34
User entered 'None (0)'	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:17', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa'	System	10 Oct 2020 05:43:34
User entered 'None (0)'	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:19', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa'	System	10 Oct 2020 05:43:34
User entered 'None (0)'	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:22', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa'	System	10 Oct 2020 05:43:34
User entered 'None (0)'	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:25', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa'	System	10 Oct 2020 05:43:34
User entered 'None (0)'	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:28', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa'	System	10 Oct 2020 05:43:34
User entered 'Yes (Y)'	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa' User entered '10 Oct 2020 01:43'	System	10 Oct 2020 05:43:34
	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 5'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:21', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09'	System	11 Oct 2020 09:59:39
User entered 'None (0)'	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:23', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09'	System	11 Oct 2020 09:59:39
User entered 'None (0)'	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09'	System	11 Oct 2020 09:59:39
User entered 'None (0)'	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09'	System	11 Oct 2020 09:59:39
User entered 'None (0)'	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:28', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09'	System	11 Oct 2020 09:59:39
User entered 'None (0)'	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09'	System	11 Oct 2020 09:59:39
User entered 'None (0)'	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09'	System	11 Oct 2020 09:59:39
User entered 'No (N)'	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09'	System	11 Oct 2020 09:59:39
User entered '11 Oct 2020 05:59'	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 6'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered 'None (0)'	System	12 Oct 2020 11:48:25
	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered 'None (0)'	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:05', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered 'None (0)'	System	12 Oct 2020 11:48:25
	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:11', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered 'None (0)'	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:13', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f'	System	12 Oct 2020 11:48:25
User entered 'None (0)'	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:14', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f'	System	12 Oct 2020 11:48:25
User entered 'None (0)'	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f'	System	12 Oct 2020 11:48:25
User entered 'No (N)'	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:20', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered '12 Oct 2020 07:48'	System	12 Oct 2020 11:48:25
	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 7'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:32:55', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450'	System	13 Oct 2020 02:33:16
User entered 'None (0)'	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:32:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450'	System	13 Oct 2020 02:33:16
User entered 'None (0)'	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:32:59', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450'	System	13 Oct 2020 02:33:16
User entered 'None (0)'	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450'	System	13 Oct 2020 02:33:16
User entered 'None (0)'	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450'	System	13 Oct 2020 02:33:16
User entered 'None (0)'	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450'	System	13 Oct 2020 02:33:16
User entered 'None (0)'	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:11', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450'	System	13 Oct 2020 02:33:16
User entered 'No (N)'	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:13', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450'	System	13 Oct 2020 02:33:16
User entered '12 Oct 2020 22:33'	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:30:02

US3532192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:30:02

US3532192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:30:02

US3532192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:30:02

US3532192

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:30:06

US3532192

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 16:30:06

US3532192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:31:47

US3532192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:31:47

US3532192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:31:47

US3532192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:31:47

US3532192

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:31:54

US3532192

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:31:54

US3532192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	28 Oct 2020 17:06:38

US3532192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Peggy Kettle (b) (4) (b) (4)	28 Oct 2020 17:06:38

US3532192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Peggy Kettle (b) (4) (b) (4)	28 Oct 2020 17:06:38

US3532192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	28 Oct 2020 17:06:38

US3532192

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	28 Oct 2020 17:06:45

US3532192

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 17:06:45

US3532192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:08

US3532192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 10:19:14
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	Etza Peters (b) (4)	11 Nov 2020 20:09:31
answered with 'confirm date' (Site from System).	(b) (4)	
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	11 Nov 2020 20:09:08
User entered '11 Nov 2020'	Etza Peters (b) (4)	11 Nov 2020 20:09:08
	(b) (4)	

US3532192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:08

US3532192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	11 Nov 2020 20:09:08

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:54

US3532192

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:54

US3532192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	11 Nov 2020 21:35:19

US3532192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Etza Peters (b) (4) (b) (4)	11 Nov 2020 21:35:19

US3532192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '15:19'	Etza Peters (b) (4) (b) (4)	11 Nov 2020 21:35:19

US3532192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '11 Nov 2020 15:19'	System	11 Nov 2020 21:35:19

US3532192

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	11 Nov 2020 21:34:29

US3532192

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:34:29

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 64'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-31T11:20:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2343170c-ac00-44a6-af19-4c064a55cd0e' User entered 'No (N)'	System	31 Oct 2020 15:20:57
	System	31 Oct 2020 15:20:57

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-31T11:20:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2343170c-ac00-44a6-af19-4c064a55cd0e'	System	31 Oct 2020 15:20:57
User entered 'No (N)'	System	31 Oct 2020 15:20:57

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-31T11:20:55', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2343170c-ac00-44a6-af19-4c064a55cd0e' User entered '31 Oct 2020 11:20:55'	System	31 Oct 2020 15:20:57
	System	31 Oct 2020 15:20:57

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 71'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-09T01:43:14', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '3a9a8f97-d1aa-4d27-812c-213c88e4bb56'	System	09 Nov 2020 06:43:25
User entered 'No (N)'	System	09 Nov 2020 06:43:25

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-09T01:43:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '3a9a8f97-d1aa-4d27-812c-213c88e4bb56'	System	09 Nov 2020 06:43:25
User entered 'No (N)'	System	09 Nov 2020 06:43:25

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-09T01:43:23', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '3a9a8f97-d1aa-4d27-812c-213c88e4bb56'	System	09 Nov 2020 06:43:25
User entered '09 Nov 2020 01:43:23'	System	09 Nov 2020 06:43:25

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 78'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-14T02:32:17', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5194225c-b467-43eb-9abf-d7232d87e7fe'	System	14 Nov 2020 07:32:32
User entered 'No (N)'	System	14 Nov 2020 07:32:32

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-14T02:32:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5194225c-b467-43eb-9abf-d7232d87e7fe'	System	14 Nov 2020 07:32:32
User entered 'No (N)'	System	14 Nov 2020 07:32:32

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-14T02:32:27', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5194225c-b467-43eb-9abf-d7232d87e7fe' User entered '14 Nov 2020 02:32:27'	System	14 Nov 2020 07:32:32
	System	14 Nov 2020 07:32:32

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Oct 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '01 Nov 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '04 Nov 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '08 Nov 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '11 Nov 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '15 Nov 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:37:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:46:28

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Nosebleed - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 19:48:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 19:48:39
Data point term sent to Coder	System	20 Oct 2020 19:48:01
User entered 'Nosebleed'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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	22 Oct 2020 20:49:33
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	22 Oct 2020 20:49:33
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	22 Oct 2020 20:48:53
User entered '20 Oct 2020'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 20:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 20:48:53
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:47:12
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 20:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 20:48:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:47:12
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 20:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 20:48:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:47:12
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 20:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 20:48:53
User entered 'None (NONE)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:47:12
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[None](#)

Audit	User	Time (GMT)
User entered '1'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:49:33
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 20:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 20:48:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:47:12
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject has history of nosebleeds since 2014. Has seen a doctor for them in the past but no known etiology. Not related to vaccine, due to prior history' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:37:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:17
User entered 'USA-US077-2020-mRNA-1273-P301000012'	System	13 Nov 2020 13:17:13
User entered 'New'	(b) (4), (b) (6)	13 Nov 2020 13:17:13

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating event term to final diagnosis, including staging.' answered with 'new diagnosis of cancer awaiting kidney removal for final staging' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:03:59
User opened query 'PV Query: Please consider updating event term to final diagnosis, including staging.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:40
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cancer, LLT: Kidney cancer - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 16:17:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 16:17:33
Data point term sent to Coder	System	12 Nov 2020 16:17:12
User entered 'kidney cancer'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered '09 Oct 2020'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6) System	20 Nov 2020 22:22:47 12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Life threatening](#)

Audit	User	Time (GMT)
User entered '1'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	12 Nov 2020 16:17:24
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		12 Nov 2020 16:17:24
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	12 Nov 2020 16:16:30
User entered '0'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Peggy Kettle (b) (4)	12 Nov 2020 16:17:24
User entered 'No (N)'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '1'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[None](#)

Audit	User	Time (GMT)
User entered '1'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'awaiting final outcome' (Site from Safety).	Laila Hussaini (b) (4) (b) (4)	24 Nov 2020 17:06:19
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	20 Nov 2020 22:22:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide Oncology notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'no notes provided by subject to date' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:08:27
Query 'PV Query: Was a biopsy performed? If so, please provide results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'no biopsy performed to date.' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:08:16
Query 'PV Query: Has the subject seen an oncologist or have plans to see one in the future? If so, what is the treatment plan?' answered with 'has oncology appointment scheduled' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:07:47
Query 'PV Query: Please provide the date of kidney removal and clarify which kidney was removed (left vs right).' answered with 'waiting for oncology appointment' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:07:36
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no updated provided by subject yet' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:07:25
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no update at the time' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:06:36
User opened query 'PV Query: Please provide Oncology notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:48
User opened query 'PV Query: Was a biopsy performed? If so, please provide results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Has the subject seen an oncologist or have plans to see one in the future? If so, what is the treatment plan?' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:23
User opened query 'PV Query: Please provide the date of kidney removal and clarify which kidney was removed (left vs right).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:17
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:09
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)	20 Nov 2020 22:23:02
User entered 'New diagnosis of cancer. Awaiting kidney removal. Diagnosed wehn he was undergoing workup for kidney transplant. Not related to vaccine. Had baseline kidney failure'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 16:16:30

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:37:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:10:39

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:45:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:45:40
Data point term sent to Coder	System	31 Aug 2020 20:44:38
Data point term sent to Coder	System	31 Aug 2020 20:28:08
User entered 'hydralazine'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) 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)	15 Oct 2020 04:12:44
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'added' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:31:52
User entered '100' reason for change: Per Query Resolution	(b) (4)	13 Oct 2020 16:31:45
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) 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)	08 Oct 2020 13:54:08
User entered '2'	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	13 Oct 2020 16:31:45
User entered 'tablet (TABLET)'	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	13 Oct 2020 16:31:45
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:44:08
User entered 'once daily (QD)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:44:08
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:27:15
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:44:08
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:44:08
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:27:15
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 05:33:40
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'corrected start date of MH' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:33:39
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:54:06
User closed query 'Start date is missing and Start date System completely unknown is not checked. Please provide.' (Site from System).		31 Aug 2020 20:44:08
User entered 'un UNK 2014' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:44:08
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	31 Aug 2020 20:27:15
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:44:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:44:08
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:27:15
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:44:08
User entered 'No (N)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:44:08
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:27:15
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Oct 2020 16:31:45
User entered '1'	System	31 Aug 2020 20:44:08
User entered empty.	System	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:44:08
User entered empty.	System	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:44:08
User entered empty.	System	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: OTHER DIURETICS, PRODUCT: ISOSORBIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:46:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:46:42
Data point term sent to Coder	System	31 Aug 2020 20:45:38
User entered 'isosorbide'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 60 MG, etc) 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)	15 Oct 2020 06:11:36
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 60 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'MH start date corrected' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:34:21
User entered '90' reason for change: Per Query Resolution	(b) (4)	13 Oct 2020 16:34:08
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 60 MG, etc) 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)	08 Oct 2020 13:54:43
User entered '3'	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:34:08
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:11:12
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'MH date corrected' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:40:43
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:54:27
User entered 'un UNK 2014'	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:46:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:46:41
Data point term sent to Coder	System	31 Aug 2020 20:45:40
User entered 'carvedilol'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25' reason for change: New Information	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:34:53
User entered '1'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: New Information	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:34:53
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:14:10
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'MH start date corrected' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:35:03
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:35:02
User entered 'un UNK 2014'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:47:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:47:44
Data point term sent to Coder	System	31 Aug 2020 20:46:41
User entered 'amlodipine'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) 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)	15 Oct 2020 04:13:12
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'added' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:35:42
User entered '10' reason for change: Per Query Resolution	(b) (4)	13 Oct 2020 16:35:35
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) 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)	08 Oct 2020 13:55:13
User entered '1'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	13 Oct 2020 16:35:35
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:14:27
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'MH start date corrected' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:35:55
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:55:22
User entered 'un UNK 2014'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Name of Medication](#)

Audit	User	Time (GMT)
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)	31 Aug 2020 20:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:49:34
Data point term sent to Coder	System	31 Aug 2020 20:47:42
User entered 'lisinopril'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 10 MG, etc) 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)	15 Oct 2020 04:13:37
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'added' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:36:30
User entered '30' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	13 Oct 2020 16:36:24
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 10 MG, etc) 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)	08 Oct 2020 13:55:54
User entered '1'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:36:24
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:15:12
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'MH start date corrected' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:36:41
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:55:46
User entered 'un UNK 2019'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 20:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 20:49:34
Data point term sent to Coder	System	31 Aug 2020 20:47:43
User entered 'potassium'	Laila Hussaini (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:28:41
Query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' answered with 'changed to prophylaxis per query request' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	17 Nov 2020 16:18:12
User entered 'Yes (Y)' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	17 Nov 2020 16:17:51
User opened query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 09:12:33
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10' reason for change: New Information	Peggy Kettle (b) (4)	13 Oct 2020 16:37:31
User entered '1'	Laila Hussaini (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)' reason for change: New Information	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:37:31
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'meq' reason for change: New Information	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:37:31
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Name of Medication](#)

Audit	User	Time (GMT)
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)	13 Oct 2020 16:40:26
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 Oct 2020 16:40:26
Data point term sent to Coder Coding entries removed.	System Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:38:49 13 Oct 2020 16:38:09
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)	03 Sep 2020 07:37:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 07:37:45
Data point term sent to Coder Coding entries removed.	System Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:25:47 03 Sep 2020 00:25:30
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)	31 Aug 2020 20:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:49:34
Data point term sent to Coder User entered 'multi-vitamin'	System Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:44 31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:28:50
Query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' answered with 'changed to prophylaxis per query request' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	17 Nov 2020 16:18:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	17 Nov 2020 16:18:22
User opened query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 09:12:45
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:16:56
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'data entry error, for general health' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:38:28
User entered 'general health' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 16:38:09
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:50:03
User entered 'HYPOKALEMIA' reason for change: Data Entry Error	Peggy Kettle (b) (4)	03 Sep 2020 00:25:30
User entered 'general health'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 05:37:02
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'data entry error, for general health' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:38:39
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:50:35
User entered 'un UNK 2014'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:18:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:18:34
Data point term sent to Coder	System	31 Aug 2020 20:49:45
User entered 'Calcium'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'chronic kidney failure'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 600 MG, etc) 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)	15 Oct 2020 04:11:43
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 600 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'added' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:39:33
User entered '1334' reason for change: Per Query Resolution	(b) (4)	13 Oct 2020 16:39:28
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 600 MG, etc) 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)	08 Oct 2020 16:35:19
User entered '2'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:39:28
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 06:06:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 06:06:34
Data point term sent to Coder	System	03 Sep 2020 00:27:49
User entered 'FUROSEMIDE (lasix)'	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'chronic kidney failure'	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 04:13:51
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'added' (Site from DM).	Peggy Kettle (b) (4)	13 Oct 2020 16:40:07
User entered '120' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	13 Oct 2020 16:40:01
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:49:44
User entered '3'	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	13 Oct 2020 16:40:01
User entered 'tablet (TABLET)'	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 00:28:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 00:28:01
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	03 Sep 2020 00:28:01
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 00:27:26
User entered empty.	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 17:21:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 17:21:52
Data point term sent to Coder	System	19 Oct 2020 12:22:15
User entered 'Tums'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'Chronic kidney failure'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 12:21:26

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'USA-US077-2020-MRNA-1273-P301000012'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Evan'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Anderson'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '2015 Uppergate Drive'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Atlanta'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'GA'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '30323'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'USA-US077-2020-MRNA-1273-P301000012'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Evan'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Anderson'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '2015 Uppergate Drive'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Site Address:](#) City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Atlanta'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'GA'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '30323'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '13/Nov/2020 08:17'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 13:17:40