

US3632022 (Prod: Grady Health System)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:09:22

All time stamps listed in this document are displayed in GMT

US3632022

Form: Participant Creation

Generated On: 26 Nov 2020 11:09:22

[Participant ID](#)

US3632022

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

US3632022

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

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

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	68
Age Units	YEARS
Age (Derived)	68
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3632022

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:22

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 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

US3632022

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:22

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3632022

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:22

Were any significant conditions reported?

Yes ☒

No ☐

US3632022

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:22

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	1 UNK 1978
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	1 UNK 1978
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1978
Start Year (derived)	1978
Stop Month and Year (derived)	JAN 1978
Stop Year (derived)	1978

US3632022

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:22

Condition	LEIOMYOSARCOMA
Start date (dd MMM yyyy)	1 UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	1 NOV 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	NOV 2017
Stop Year (derived)	2017

US3632022

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:22

Condition	HIP REPLACEMENT (RIGHT)
Start date (dd MMM yyyy)	1 APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	1 APR 2018
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	APR 2018
Stop Year (derived)	2018

US3632022

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:22

Condition	PARTIAL SCALP REMOVAL
Start date (dd MMM yyyy)	1 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	1 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3632022

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:22

Condition	INSOMNIA
Start date (dd MMM yyyy)	1 DEC 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3632022

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:22

Condition	ANXIETY
Start date (dd MMM yyyy)	1 DEC 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3632022

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:22

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	1 UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3632022

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:22

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	01 UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

US3632022

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:22

Condition	AVASCULAR NECROSIS IN RIGHT HIP
Start date (dd MMM yyyy)	01 UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 APR 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	APR 2018
Stop Year (derived)	2018

US3632022

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:22

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	01 UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:03 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:03
Height (<i>xxx.x</i>)	171 cm
Weight (<i>xxx.x</i>)	57.1526 kg
BMI (<i>xxx.x</i>)	19.54536 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)	

US3632022

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3632022

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:22

Date of assessment (<i>dd MMM yyyy</i>)	28 AUG 2020
Is the participant of childbearing potential?	Yes ☐
	No ☒
If No, what is the reason?	Surgically sterile ☐
	Post-menopausal ☒
	Partner medically sterile ☐
	Not reached age of Menarche ☐
	Other ☐
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	01 UNK 2003
Date of last menstruation unknown	False

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

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

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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)	False
Other	False
Specify	

US3632022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3632022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:22

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 187945

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 ☒

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:22

Height	ND - Not Done
Weight	ND - Not Done

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

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)	28 AUG 2020
Time of assessment (00:00-23:59)	15:03 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:03
Temperature (xxx.x)	96.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

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)	28 AUG 2020
Time of assessment (00:00-23:59)	17:19 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 17:19
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3632022

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3632022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	28 AUG 2020
What was the treatment time? (00:00-23:59)	16:46 (24 HR)
Treatment Date and Time (derived)	28 AUG 2020 16:46
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

US3632022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

28 AUG 2020

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

15:36 (24 HR)

Collection date and time (derived)

28 AUG 2020 15:36

US3632022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:22

Collection date (<i>dd MMM yyyy</i>)			28 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	15:11	28 AUG 2020 15:11
Nasopharyngeal Swab 2	No		

US3632022

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

28 AUG 2020 17:27

PC Open Date & Time

28 AUG 2020 17:06

PC Close Date & Time

28 AUG 2020 19:36

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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

97.2 °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 28 AUG 2020 20:46

PC Open Date & Time 28 AUG 2020 20:31

PC Close Date & Time 29 AUG 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

29 AUG 2020 21:42

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

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

97.2 °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

30 AUG 2020 20:14

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 20:32

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 20:00

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp 02 SEP 2020 21:01

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 23:01

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 17:27

PC Open Date & Time

28 AUG 2020 17:06

PC Close Date & Time

28 AUG 2020 19:36

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:46

PC Open Date & Time

28 AUG 2020 20:31

PC Close Date & Time

29 AUG 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 21:43

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 20:14

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 20:33

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 20:01

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

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

02 SEP 2020 21:01

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 23:01

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 17:27
PC Open Date & Time	28 AUG 2020 17:06
PC Close Date & Time	28 AUG 2020 19:36

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 20:45
PC Open Date & Time	28 AUG 2020 20:31
PC Close Date & Time	29 AUG 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

Yes ☐	
PC Time stamp	29 AUG 2020 21:43
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

Yes ☐	
PC Time stamp	30 AUG 2020 20:15
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

Yes ☐	
PC Time stamp	31 AUG 2020 20:33
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

Yes ☐	
PC Time stamp	01 SEP 2020 20:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

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

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

Yes ☐	
PC Time stamp	03 SEP 2020 23:01
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3632022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

Was Contact Attempted?

Yes ☒

No ☐

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

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632022

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632022

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632022

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	12:04 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 12:04
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	14:33 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 14:33
Temperature (xxx.x)	96.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3632022

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3632022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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) 25 SEP 2020

What was the treatment time? (00:00-23:59) 14:01 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 14:01

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

US3632022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	25 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:02 (24 HR)
Collection date and time (derived)	25 SEP 2020 13:02

US3632022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:22

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:05	25 SEP 2020 13:05
Nasopharyngeal Swab 2	No		

US3632022

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp 25 SEP 2020 14:31

PC Open Date & Time 25 SEP 2020 14:21

PC Close Date & Time 25 SEP 2020 16:51

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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 25 SEP 2020 20:52

PC Open Date & Time 25 SEP 2020 17:46

PC Close Date & Time 26 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 13:36

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

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

97.2 °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

27 SEP 2020 12:08

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 12:43

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 12:37

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 14:16

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp 01 OCT 2020 12:00

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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

25 SEP 2020 14:32

PC Open Date & Time

25 SEP 2020 14:21

PC Close Date & Time

25 SEP 2020 16:51

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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

25 SEP 2020 20:52

PC Open Date & Time

25 SEP 2020 17:46

PC Close Date & Time

26 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

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

26 SEP 2020 13:36

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

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

27 SEP 2020 12:09

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

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

28 SEP 2020 12:43

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

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

29 SEP 2020 12:37

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

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

30 SEP 2020 14:16

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 12:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 14:32
PC Open Date & Time	25 SEP 2020 14:21
PC Close Date & Time	25 SEP 2020 16:51

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 20:53
PC Open Date & Time	25 SEP 2020 17:46
PC Close Date & Time	26 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

Yes ☐	
PC Time stamp	26 SEP 2020 13:36
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

Yes ☐	
PC Time stamp	27 SEP 2020 12:09
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

Yes ☐	
PC Time stamp	28 SEP 2020 12:43
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

Yes ☐	
PC Time stamp	29 SEP 2020 12:38
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

Yes ☐	
PC Time stamp	30 SEP 2020 14:16
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

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 ☒

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

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

US3632022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632022

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632022

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632022

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

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)	

US3632022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

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.

US3632022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	29 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:16 (24 HR)
Collection date and time (derived)	29 OCT 2020 10:16

US3632022

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

29 OCT 2020 12:15:45

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

04 NOV 2020 14:18:52

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

13 NOV 2020 12:01:01

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	23 NOV 2020 09:34:56
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2020 00:01

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31 DEC 2020 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

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07 JAN 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

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28 JAN 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

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18 FEB 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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28 FEB 2021 00:01

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04 MAR 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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18 MAR 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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21 MAR 2021 00:01

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25 MAR 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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28 MAR 2021 00:01

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01 APR 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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08 APR 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

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15 APR 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

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06 MAY 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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13 MAY 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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07 NOV 2021 00:01

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11 NOV 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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14 NOV 2021 00:01

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18 NOV 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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°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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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 MAR 2022 00:01

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10 MAR 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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31 MAR 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

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14 APR 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

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21 APR 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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12 MAY 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

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19 MAY 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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09 JUN 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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16 JUN 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

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23 JUN 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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26 JUN 2022 00:01

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30 JUN 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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03 JUL 2022 00:01

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07 JUL 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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10 JUL 2022 00:01

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14 JUL 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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21 JUL 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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28 JUL 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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04 AUG 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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07 AUG 2022 00:01

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11 AUG 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

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18 AUG 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

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21 AUG 2022 00:01

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25 AUG 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3632022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632022

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

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

US3632022

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3632022

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:09:22

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3632022

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:22

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

AEID	USA-US120-2020-MRNA-1273-P30 1000006
Adverse event	METASTATIC LEIOMYOSARCOMA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	20 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	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)

342 of 1648

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT WAS INITIALLY DIAGNOSED WITH LEIOMYOSARCOMA IN 2017. DURING ROUTINE IMAGING, SHE WAS FOUND TO HAVE METASTATIC DISEASE TO HER LIVER. SHE IS CURRENTLY ASYMPTOMATIC.
Serious Adverse Event Derived (CSA Programming Field Only)	1

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

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

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:22

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

Yes ☒

No ☐

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

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

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

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

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

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

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

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

	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)	1 UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

Name of Medication	CALCIUM AND VITAMIN D
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOPOROSIS
Dose per administration	600/400IU
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 ☐

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

	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)		1 UNK 2010
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

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

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

	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)		1 UNK 2010
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:09:22

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3632022

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:22

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

US3632022

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:22

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 ☐

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

SAEID	USA-US120-2020-MRNA-1273-P301000006
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:22

SAEID	USA-US120-2020-MRNA-1273-P301000006
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	24/NOV/2020 13:47
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

US3632022 (Prod: Grady Health System)

US3632022

Form: Participant Creation

Generated On: 26 Nov 2020 11:09:22

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3632022'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 18:24:44

US3632022

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	28 Aug 2020 20:35:22
	(b) (4)	

US3632022

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 18:24:45

US3632022

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Bezuayehu Mandefro	28 Aug 2020 20:35:22
	(b) (4)	

US3632022

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	28 Aug 2020 20:35:22

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1951'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 18:24:46

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

[Age](#)

Audit	User	Time (GMT)
User entered '68'	Bezuayehu Mandefro	28 Aug 2020 20:36:13
	(b) (4)	

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	28 Aug 2020 20:36:13

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '68'	System	28 Aug 2020 20:36:55

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Bezuayehu Mandefro	28 Aug 2020 20:36:13
	(b) (4)	

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

[Ethnicity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 20:36:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 20:36:31
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' reason for change: New Information	Bezuayehu Mandefro (b) (4)	28 Aug 2020 20:36:31
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 20:36:13
User entered empty.	Bezuayehu Mandefro (b) (4)	28 Aug 2020 20:36:13

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

White

Audit	User	Time (GMT)
User entered '1'	Bezuayehu Mandefro	28 Aug 2020 20:36:13
	(b) (4)	

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:36:13
	(b) (4)	

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:36:13
	(b) (4)	

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:36:13
	(b) (4)	

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:36:13
	(b) (4)	

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:36:13
	(b) (4)	

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	28 Aug 2020 20:36:13
	(b) (4)	

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

Unknown

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:36:13
	(b) (4)	

US3632022

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:22

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:36:13
	(b) (4)	

US3632022

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:22

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Bezuayehu Mandefro	28 Aug 2020 20:36:55
	(b) (4)	

US3632022

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	28 Aug 2020 20:36:55

US3632022

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2020'	System	28 Aug 2020 20:36:55

US3632022

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:22

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Bezuayehu Mandefro	28 Aug 2020 20:36:55
	(b) (4)	

US3632022

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	28 Aug 2020 20:36:55
	(b) (4)	

US3632022

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:22

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro (b) (4)	28 Aug 2020 20:36:55

US3632022

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:22

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro (b) (4) 	28 Aug 2020 20:36:55

US3632022

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:22

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	28 Aug 2020 20:36:55

US3632022

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:22

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 18:24:45

US3632022

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:22

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 20:37:01

US3632022

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:22

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	28 Aug 2020 20:37:01
	(b) (4)	

US3632022

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:22

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 16:57:37
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:37:10
	(b) (4)	

US3632022

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 16:59:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 16:59:49
Data point term sent to Coder	System	02 Sep 2020 16:58:49
User entered 'Tonsillectomy'	(b) (4), (b) (6) (b) (4)	02 Sep 2020 16:58:11

US3632022

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 UNK 1978'	(b) (4), (b) (6)	02 Sep 2020 16:58:11

US3632022

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:58:11

US3632022

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:58:11

US3632022

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 UNK 1978'	(b) (4), (b) (6)	02 Sep 2020 16:58:11

US3632022

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:58:11

US3632022

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Jan 1978'	System	02 Sep 2020 16:58:11

US3632022

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1978'	System	02 Sep 2020 16:58:11

US3632022

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Jan 1978'	System	02 Sep 2020 16:58:11

US3632022

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1978'	System	02 Sep 2020 16:58:11

US3632022

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Soft tissue neoplasms malignant and unspecified, HLT: Leiomyosarcomas, PT: Leiomyosarcoma, LLT: Leiomyosarcoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:00:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:00:52
Data point term sent to Coder	System	02 Sep 2020 16:59:50
User entered 'Leiomyosarcoma'	(b) (4), (b) (6) (b) (4)	02 Sep 2020 16:58:58

US3632022

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 UNK 2017'	(b) (4), (b) (6)	02 Sep 2020 16:58:58

US3632022

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:58:58

US3632022

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:58:58

US3632022

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 Nov 2017'	(b) (4), (b) (6)	02 Sep 2020 16:58:58

US3632022

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:58:58

US3632022

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	02 Sep 2020 16:58:58

US3632022

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2017'	System	02 Sep 2020 16:58:58

US3632022

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Nov 2017'	System	02 Sep 2020 16:58:58

US3632022

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2017'	System	02 Sep 2020 16:58:58

US3632022

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:22

[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)	20 Oct 2020 07:32:57
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 'Due to Osteo Arthritis diagnosed in 2015 and Avascular Necrosis diagnosed in 2018. ' (Site from DM).	Sarah Wiatrek (b) (4)	16 Oct 2020 14:19:32
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)	13 Oct 2020 05:58:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 22:16:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 22:16:53
Data point term sent to Coder	System	02 Sep 2020 17:00:53
User entered 'Hip Replacement (Right)'	(b) (4), (b) (6)	02 Sep 2020 17:00:17

US3632022

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 Apr 2018'	(b) (4), (b) (6)	02 Sep 2020 17:00:17

US3632022

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:00:17

US3632022

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:00:17

US3632022

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 Apr 2018'	(b) (4), (b) (6)	02 Sep 2020 17:00:17

US3632022

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:00:17

US3632022

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Apr 2018'	System	02 Sep 2020 17:00:17

US3632022

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Sep 2020 17:00:17

US3632022

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Apr 2018'	System	02 Sep 2020 17:00:17

US3632022

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2018'	System	02 Sep 2020 17:00:17

US3632022

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:22

[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)	22 Oct 2020 15:57:02
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 'Procedure is associated with the Leiomyosarcoma diagnosis from 2017. ' (Site from DM).	Sarah Wiatrek (b) (4)	16 Oct 2020 12:53:37
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)	13 Oct 2020 05:59:45
Data point term sent to Coder	System	02 Sep 2020 17:00:56
User entered 'Partial Scalp Removal'	(b) (4), (b) (6)	02 Sep 2020 17:00:51

US3632022

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 Jul 2020'	(b) (4), (b) (6)	02 Sep 2020 17:00:51

US3632022

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:00:51

US3632022

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:00:51

US3632022

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 Jul 2020'	(b) (4), (b) (6)	02 Sep 2020 17:00:51

US3632022

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:00:51

US3632022

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	02 Sep 2020 17:00:51

US3632022

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Sep 2020 17:00:51

US3632022

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	02 Sep 2020 17:00:51

US3632022

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Sep 2020 17:00:51

US3632022

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:22

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:02:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:02:43
Data point term sent to Coder	System	02 Sep 2020 17:01:57
User entered 'Insomnia'	(b) (4), (b) (6)	02 Sep 2020 17:01:12

US3632022

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 Dec 2017'	(b) (4), (b) (6)	02 Sep 2020 17:01:12

US3632022

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:01:12

US3632022

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 17:01:12

US3632022

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:01:12

US3632022

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:01:12

US3632022

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Dec 2017'	System	02 Sep 2020 17:01:12

US3632022

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2017'	System	02 Sep 2020 17:01:12

US3632022

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:01:12

US3632022

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:01:12

US3632022

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:02:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:02:43
Data point term sent to Coder	System	02 Sep 2020 17:01:57
User entered 'Anxiety'	(b) (4), (b) (6)	02 Sep 2020 17:01:30

US3632022

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 Dec 2017'	(b) (4), (b) (6)	02 Sep 2020 17:01:30

US3632022

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:01:30

US3632022

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 17:01:30

US3632022

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:01:30

US3632022

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:01:30

US3632022

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Dec 2017'	System	02 Sep 2020 17:01:30

US3632022

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2017'	System	02 Sep 2020 17:01:30

US3632022

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:01:30

US3632022

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:01:30

US3632022

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:02:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:02:44
Data point term sent to Coder	System	02 Sep 2020 17:01:57
User entered 'Osteoporosis'	(b) (4), (b) (6) (b) (4)	02 Sep 2020 17:01:52

US3632022

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 UNK 2020'	(b) (4), (b) (6)	02 Sep 2020 17:01:52

US3632022

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:01:52

US3632022

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 17:01:52

US3632022

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:01:52

US3632022

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:01:52

US3632022

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	02 Sep 2020 17:01:52

US3632022

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Sep 2020 17:01:52

US3632022

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:01:52

US3632022

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:01:52

US3632022

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 13:38:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	09 Oct 2020 13:38:32
Data point term sent to Coder	System	09 Oct 2020 13:37:16
User entered 'POSTMENOPAUSAL'	Kelly Likos (b) (4)	09 Oct 2020 13:36:53
	(b) (4)	

US3632022

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '01 UNK 2003'	Kelly Likos (b) (4) (b) (4)	09 Oct 2020 13:36:53

US3632022

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	09 Oct 2020 13:36:53

US3632022

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	09 Oct 2020 13:36:53

US3632022

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	Kelly Likos (b) (4) (b) (4)	09 Oct 2020 13:36:53

US3632022

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	09 Oct 2020 13:36:53

US3632022

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	09 Oct 2020 13:36:53

US3632022

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2003'	System	09 Oct 2020 13:36:53

US3632022

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 13:36:53

US3632022

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 13:36:53

US3632022

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Osteonecrosis, LLT: Avascular necrosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:26:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:26:30
Data point term sent to Coder	System	16 Oct 2020 14:21:01
User entered 'Avascular Necrosis in Right Hip'	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:20:49

US3632022

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '01 UNK 2018' reason for change: Data Entry Error	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:21:01
User entered '01 Apr 2018'	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:20:49

US3632022

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:20:49

US3632022

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:20:49

US3632022

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '01 Apr 2018'	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:20:49

US3632022

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:20:49

US3632022

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	16 Oct 2020 14:21:01
User entered 'Apr 2018'	System	16 Oct 2020 14:20:49

US3632022

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2018'	System	16 Oct 2020 14:20:49

US3632022

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Apr 2018'	System	16 Oct 2020 14:20:49

US3632022

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2018'	System	16 Oct 2020 14:20:49

US3632022

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 19:51:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 19:51:36
Data point term sent to Coder	System	27 Oct 2020 19:50:43
User entered 'Osteopenia'	Bezuayehu Mandefro (b) (4)	27 Oct 2020 19:50:36

US3632022

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '01 UNK 2010'	Bezuayehu Mandefro	27 Oct 2020 19:50:36
	(b) (4)	

US3632022

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	27 Oct 2020 19:50:36
	(b) (4)	

US3632022

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	27 Oct 2020 19:50:36
	(b) (4)	

US3632022

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '01 Jul 2020'	Bezuayehu Mandefro	27 Oct 2020 19:50:36
	(b) (4)	

US3632022

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	27 Oct 2020 19:50:36
	(b) (4)	

US3632022

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	27 Oct 2020 19:50:36

US3632022

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2010'	System	27 Oct 2020 19:50:36

US3632022

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	27 Oct 2020 19:50:36

US3632022

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '2020'	System	27 Oct 2020 19:50:36

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	28 Aug 2020 20:38:21
	(b) (4)	

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Bezuayehu Mandefro	28 Aug 2020 20:38:21
	(b) (4)	

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '15:03'	Bezuayehu Mandefro	28 Aug 2020 20:38:21
	(b) (4)	

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:03'	System	28 Aug 2020 20:38:21

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm if value of 171 IN is correct, as this is an unexpected value for Height. Thank you' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 18:22:50
Query 'Per CDM: Please confirm if value of 171 IN is correct, as this is an unexpected value for Height. Thank you' answered with 'Data entry error - corrected to reflect the height as 171 CM.' (Site from DM).	Kelly Likos (b) (4) (b) (4)	03 Sep 2020 17:45:02
User entered '171' cm reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	03 Sep 2020 17:43:26
User opened query 'Per CDM: Please confirm if value of 171 IN is correct, as this is an unexpected value for Height. Thank you' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 17:42:02
User entered '171' in	Bezuayehu Mandefro (b) (4)	28 Aug 2020 20:38:21
DataPoint set to visible.	System	28 Aug 2020 20:37:01

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '57.1526' kg reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 16:51:55
User entered '126' lb	Bezuayehu Mandefro	28 Aug 2020 20:38:21
	(b) (4)	
DataPoint set to visible.	System	28 Aug 2020 20:37:01

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '19.54536'	System	03 Sep 2020 17:43:26
User entered '3.02954'	System	02 Sep 2020 16:51:55
User entered '3.03591'	System	28 Aug 2020 20:38:21
DataPoint set to visible.	System	28 Aug 2020 20:37:01

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	28 Aug 2020 20:38:21
DataPoint set to visible.	System	28 Aug 2020 20:37:01

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Re-query: ND (Not done) noted for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP, however, please also keep the Units blank for all the data-fields. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 06:24:39
Query 'Per CDM: Re-query: ND (Not done) noted for Isaac Perez PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP, however, please also keep the Units blank for all the data-fields. Thank you.' answered with 'Units have been left blank.' (Site from DM).	(b) (4) (b) (4)	17 Sep 2020 14:48:07
User opened query 'Per CDM: Re-query: ND (Not done) noted for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP, however, please also keep the Units blank for all the data-fields. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:36:03
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:36:03
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'Changed to ND' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:58:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:18:23
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 16:26:44
v6.020 DTW (1102)		500 of 1648

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.5' F	Bezuayehu Mandefro	28 Aug 2020 20:38:21
	(b) (4)	

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:18:23
User entered 'Oral (Oral)'	Bezuayehu Mandefro	28 Aug 2020 20:38:21
	(b) (4)	

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	28 Aug 2020 20:38:21
	(b) (4)	

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:18:23
User entered '62'	Bezuayehu Mandefro	28 Aug 2020 20:38:21
	(b) (4)	

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Aug 2020 20:38:21

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:18:23
User entered '14'	Bezuayehu Mandefro	28 Aug 2020 20:38:21
	(b) (4)	

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Aug 2020 20:38:21

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:18:23
User entered '104'	Bezuayehu Mandefro	28 Aug 2020 20:38:21
	(b) (4)	

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 20:38:21

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:18:23
User entered '62'	Bezuayehu Mandefro	28 Aug 2020 20:38:21
	(b) (4)	

US3632022

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Aug 2020 20:38:21

US3632022

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	28 Aug 2020 20:38:39
	(b) (4)	

US3632022

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Bezuayehu Mandefro	28 Aug 2020 20:38:39
	(b) (4)	

US3632022

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Bezuayehu Mandefro	28 Aug 2020 20:39:10
	(b) (4)	

US3632022

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:39:10
	(b) (4)	

US3632022

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:22

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:30:04
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Kelly Likos (b) (4)	09 Oct 2020 13:37:17
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 00:04:06
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Bezuayehu Mandefro (b) (4)	28 Aug 2020 20:39:10

US3632022

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:22

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	28 Aug 2020 20:39:10
	(b) (4)	

US3632022

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	28 Aug 2020 20:39:10
	(b) (4)	

US3632022

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:22

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:39:10
	(b) (4)	

US3632022

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '01 UNK 2003'	Bezuayehu Mandefro	28 Aug 2020 20:39:10
	(b) (4)	

US3632022

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:22

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:39:10
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro (b) (4) 	28 Aug 2020 20:39:44

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	28 Aug 2020 20:39:44

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	28 Aug 2020 20:39:44

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:22

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	28 Aug 2020 20:39:44
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	28 Aug 2020 20:40:10
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Bezuayehu Mandefro	28 Aug 2020 20:40:10
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Bezuayehu Mandefro	28 Aug 2020 20:40:10
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	28 Aug 2020 20:40:10

US3632022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Aug 2020 19:29:46

US3632022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '187945'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Aug 2020 19:29:46

US3632022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 19:29:46

US3632022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:22

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)'	Bezuayehu Mandefro (b) (4)	28 Aug 2020 20:40:26

US3632022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:40:26
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	28 Aug 2020 20:40:26

US3632022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:22

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro	28 Aug 2020 20:40:26
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:22

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Bezuayehu Mandefro (b) (4) 	28 Aug 2020 20:40:26

US3632022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Likos (b) (4)	09 Oct 2020 13:37:24
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 08:31:09
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:31:08

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:22

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:35:44
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Changed to ND' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:01:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:06:04
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 16:25:38
User entered '171' cm	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:22

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:06:04
User entered '57.1526' kg	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:22

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:35:44
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Changed to ND' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:01:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:06:04
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 16:25:38
User entered '171' cm	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:22

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:06:04
User entered '57.1526' kg	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '15:03'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:03'	System	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 18:29:30
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Isaac Perez (b) (4)	17 Sep 2020 14:48:40
answered with 'Temperature was NCS' (Site from System).	(b) (4)	
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:10:07
User entered '96.5' F	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '104'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '62'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:22

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:35:44
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Changed to ND' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:01:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:06:04
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 16:25:38
User entered '171' cm	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:22

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:06:04
User entered '57.1526' kg	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '17:19'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 17:19'	System	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '110'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '61'	(b) (4), (b) (6)	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 16:55:46

US3632022

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:55:59

US3632022

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 16:55:59

US3632022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	28 Aug 2020 21:25:10
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	28 Aug 2020 21:25:10
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	28 Aug 2020 21:25:10
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 21:25:10

US3632022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Bezuayehu Mandefro	28 Aug 2020 21:25:10
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '16:46'	Bezuayehu Mandefro	28 Aug 2020 21:25:10
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:46'	System	28 Aug 2020 21:25:10

US3632022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Bezuayehu Mandefro	28 Aug 2020 21:25:10
	(b) (4)	

US3632022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	28 Aug 2020 21:25:10

US3632022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 21:25:10

US3632022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:56:55

US3632022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 16:56:55

US3632022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 18:10:28
User entered '15:36' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 18:10:28
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 16:56:55
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:56:55

US3632022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:36'	System	02 Sep 2020 18:10:28
User entered empty.	System	02 Sep 2020 16:56:55

US3632022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 16:57:09

US3632022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:22

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Sep 2020 16:57:09

US3632022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:57:09

US3632022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:22

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	02 Sep 2020 18:10:44
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	02 Sep 2020 18:10:44
User entered '15:11' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 18:10:44
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	02 Sep 2020 16:57:09
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:57:09

US3632022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:11'	System	02 Sep 2020 18:10:44
User entered empty.	System	02 Sep 2020 16:57:09

US3632022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:22

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Sep 2020 16:57:09

US3632022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 18:10:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 18:10:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 18:10:44
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 16:57:09
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:57:09

US3632022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:57:09

US3632022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 16:57:09

US3632022

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:57:21

US3632022

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 16:57:21

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:26:44', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'e10fe095-837f-41a9-9e1e-bac1dc6563d7'	System	28 Aug 2020 21:27:10
User entered 'Yes (Y)'	System	28 Aug 2020 21:27:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:26:51', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'e10fe095-837f-41a9-9e1e-bac1dc6563d7'	System	28 Aug 2020 21:27:10
User entered '98.1'	System	28 Aug 2020 21:27:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:26:55', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'e10fe095-837f-41a9-9e1e-bac1dc6563d7'	System	28 Aug 2020 21:27:10
User entered 'No (N)'	System	28 Aug 2020 21:27:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:04', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'e10fe095-837f-41a9-9e1e-bac1dc6563d7'	System	28 Aug 2020 21:27:10
User entered '28 Aug 2020 17:27'	System	28 Aug 2020 21:27:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 17:06'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 19:36'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:33:09', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'ee43058c-3891-439b-88f6-46f655d768ae'	System	29 Aug 2020 00:46:09
User entered 'Yes (Y)'	System	29 Aug 2020 00:46:09

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:45:56', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'ee43058c-3891-439b-88f6-46f655d768ae'	System	29 Aug 2020 00:46:09
User entered '97.2'	System	29 Aug 2020 00:46:09

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:45:43', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'ee43058c-3891-439b-88f6-46f655d768ae'	System	29 Aug 2020 00:46:09
User entered 'No (N)'	System	29 Aug 2020 00:46:09

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:46:04', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'ee43058c-3891-439b-88f6-46f655d768ae'	System	29 Aug 2020 00:46:09
User entered '28 Aug 2020 20:46'	System	29 Aug 2020 00:46:09

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 20:31'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 2'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:42:32', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'cab22453-c78d-40f9-96b3-d48c5bf7d1e0'	System	30 Aug 2020 01:42:50
User entered 'Yes (Y)'	System	30 Aug 2020 01:42:50

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:42:39', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'cab22453-c78d-40f9-96b3-d48c5bf7d1e0'	System	30 Aug 2020 01:42:50
User entered '96.8'	System	30 Aug 2020 01:42:50

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:42:43', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'cab22453-c78d-40f9-96b3-d48c5bf7d1e0'	System	30 Aug 2020 01:42:50
User entered 'No (N)'	System	30 Aug 2020 01:42:50

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:42:48', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'cab22453-c78d-40f9-96b3-d48c5bf7d1e0'	System	30 Aug 2020 01:42:50
User entered '29 Aug 2020 21:42'	System	30 Aug 2020 01:42:50

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 3'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:14:10', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '8bdb0922-4d86-4c69-a538-7fe6f6697d85'	System	31 Aug 2020 00:15:56
User entered 'Yes (Y)'	System	31 Aug 2020 00:15:56

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:14:21', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '8bdb0922-4d86-4c69-a538-7fe6f6697d85'	System	31 Aug 2020 00:15:56
User entered '97.2'	System	31 Aug 2020 00:15:56

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:14:25', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '8bdb0922-4d86-4c69-a538-7fe6f6697d85'	System	31 Aug 2020 00:15:56
User entered 'No (N)'	System	31 Aug 2020 00:15:56

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:14:29', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '8bdb0922-4d86-4c69-a538-7fe6f6697d85'	System	31 Aug 2020 00:15:56
User entered '30 Aug 2020 20:14'	System	31 Aug 2020 00:15:56

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 4'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:32:38', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'df18fc73-6a8f-459f-bbb8-49542185c951'	System	01 Sep 2020 00:33:03
User entered 'Yes (Y)'	System	01 Sep 2020 00:33:03

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:32:45', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'df18fc73-6a8f-459f-bbb8-49542185c951'	System	01 Sep 2020 00:33:03
User entered '97.0'	System	01 Sep 2020 00:33:03

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:32:51', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'df18fc73-6a8f-459f-bbb8-49542185c951'	System	01 Sep 2020 00:33:03
User entered 'No (N)'	System	01 Sep 2020 00:33:03

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:32:56', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'df18fc73-6a8f-459f-bbb8-49542185c951'	System	01 Sep 2020 00:33:03
User entered '31 Aug 2020 20:32'	System	01 Sep 2020 00:33:03

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 5'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:00:39', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9e85719d-0d75-4e22-b313-889c26e5ae43'	System	02 Sep 2020 00:01:43
User entered 'Yes (Y)'	System	02 Sep 2020 00:01:43

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:00:46', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9e85719d-0d75-4e22-b313-889c26e5ae43'	System	02 Sep 2020 00:01:43
User entered '96.8'	System	02 Sep 2020 00:01:43

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:00:49', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9e85719d-0d75-4e22-b313-889c26e5ae43'	System	02 Sep 2020 00:01:43
User entered 'No (N)'	System	02 Sep 2020 00:01:43

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:00:55', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9e85719d-0d75-4e22-b313-889c26e5ae43'	System	02 Sep 2020 00:01:43
User entered '01 Sep 2020 20:00'	System	02 Sep 2020 00:01:43

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 6'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:01:17', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '770dacf0-aba5-4a1f-bef5-fd6071175c00'	System	03 Sep 2020 01:01:39
User entered 'Yes (Y)'	System	03 Sep 2020 01:01:39

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:01:24', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '770dacf0-aba5-4a1f-bef5-fd6071175c00'	System	03 Sep 2020 01:01:39
User entered '97.1'	System	03 Sep 2020 01:01:39

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:01:28', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '770dacf0-aba5-4a1f-bef5-fd6071175c00'	System	03 Sep 2020 01:01:39
User entered 'No (N)'	System	03 Sep 2020 01:01:39

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:01:32', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '770dacf0-aba5-4a1f-bef5-fd6071175c00'	System	03 Sep 2020 01:01:39
User entered '02 Sep 2020 21:01'	System	03 Sep 2020 01:01:39

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 7'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:00:54', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'add2b54a-42bb-4309-88ae-51f93aa9b7f5'	System	04 Sep 2020 03:01:18
User entered 'Yes (Y)'	System	04 Sep 2020 03:01:18

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:03', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'add2b54a-42bb-4309-88ae-51f93aa9b7f5'	System	04 Sep 2020 03:01:18
User entered '96.8'	System	04 Sep 2020 03:01:18

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:06', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'add2b54a-42bb-4309-88ae-51f93aa9b7f5'	System	04 Sep 2020 03:01:18
User entered 'No (N)'	System	04 Sep 2020 03:01:18

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:11', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'add2b54a-42bb-4309-88ae-51f93aa9b7f5'	System	04 Sep 2020 03:01:18
User entered '03 Sep 2020 23:01'	System	04 Sep 2020 03:01:18

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:40', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2e6bf4ac-9da4-4ccc-b692-d711209cd69d'	System	28 Aug 2020 21:27:56
User entered 'None (1)'	System	28 Aug 2020 21:27:56

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:43', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2e6bf4ac-9da4-4ccc-b692-d711209cd69d'	System	28 Aug 2020 21:27:56
User entered 'No (N)'	System	28 Aug 2020 21:27:56

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:45', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2e6bf4ac-9da4-4ccc-b692-d711209cd69d'	System	28 Aug 2020 21:27:56
User entered 'No (N)'	System	28 Aug 2020 21:27:56

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:49', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2e6bf4ac-9da4-4ccc-b692-d711209cd69d'	System	28 Aug 2020 21:27:56
User entered 'None (1)'	System	28 Aug 2020 21:27:56

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:53', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2e6bf4ac-9da4-4ccc-b692-d711209cd69d'	System	28 Aug 2020 21:27:56
User entered '28 Aug 2020 17:27'	System	28 Aug 2020 21:27:56

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 17:06'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 19:36'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:46:09', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b97d83f1-b240-4c7d-834a-6be52e500494'	System	29 Aug 2020 00:46:30
User entered 'None (1)'	System	29 Aug 2020 00:46:30

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:46:12', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b97d83f1-b240-4c7d-834a-6be52e500494'	System	29 Aug 2020 00:46:30
User entered 'No (N)'	System	29 Aug 2020 00:46:30

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:46:14', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b97d83f1-b240-4c7d-834a-6be52e500494'	System	29 Aug 2020 00:46:30
User entered 'No (N)'	System	29 Aug 2020 00:46:30

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:46:17', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b97d83f1-b240-4c7d-834a-6be52e500494'	System	29 Aug 2020 00:46:30
User entered 'None (1)'	System	29 Aug 2020 00:46:30

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:46:26', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b97d83f1-b240-4c7d-834a-6be52e500494'	System	29 Aug 2020 00:46:30
User entered '28 Aug 2020 20:46'	System	29 Aug 2020 00:46:30

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 20:31'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 2'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:42:53', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '44dbcec1-4f52-425c-adec-be74c1e8e87a'	System	30 Aug 2020 01:43:14
User entered 'None (1)'	System	30 Aug 2020 01:43:14

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:42:56', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '44dbcec1-4f52-425c-adec-be74c1e8e87a'	System	30 Aug 2020 01:43:14
User entered 'No (N)'	System	30 Aug 2020 01:43:14

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:42:58', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '44dbcec1-4f52-425c-adec-be74c1e8e87a'	System	30 Aug 2020 01:43:14
User entered 'No (N)'	System	30 Aug 2020 01:43:14

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:43:01', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '44dbcec1-4f52-425c-adec-be74c1e8e87a'	System	30 Aug 2020 01:43:14
User entered 'None (1)'	System	30 Aug 2020 01:43:14

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:43:11', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '44dbcec1-4f52-425c-adeb-be74c1e8e87a'	System	30 Aug 2020 01:43:14
User entered '29 Aug 2020 21:43'	System	30 Aug 2020 01:43:14

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 3'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:14:34', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd3324dad-165b-4e21-9b5f-3c9f9578abb7'	System	31 Aug 2020 00:16:04
User entered 'None (1)'	System	31 Aug 2020 00:16:04

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:14:37', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd3324dad-165b-4e21-9b5f-3c9f9578abb7'	System	31 Aug 2020 00:16:04
User entered 'No (N)'	System	31 Aug 2020 00:16:04

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:14:40', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd3324dad-165b-4e21-9b5f-3c9f9578abb7'	System	31 Aug 2020 00:16:04
User entered 'No (N)'	System	31 Aug 2020 00:16:04

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:14:43', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd3324dad-165b-4e21-9b5f-3c9f9578abb7'	System	31 Aug 2020 00:16:04
User entered 'None (1)'	System	31 Aug 2020 00:16:04

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:14:51', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd3324dad-165b-4e21-9b5f-3c9f9578abb7'	System	31 Aug 2020 00:16:04
User entered '30 Aug 2020 20:14'	System	31 Aug 2020 00:16:04

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 4'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:00', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1a01524e-8721-4dc2-bdfe-69cf86014374'	System	01 Sep 2020 00:33:23
User entered 'None (1)'	System	01 Sep 2020 00:33:23

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:04', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1a01524e-8721-4dc2-bdfe-69cf86014374'	System	01 Sep 2020 00:33:23
User entered 'No (N)'	System	01 Sep 2020 00:33:23

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:06', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1a01524e-8721-4dc2-bdfe-69cf86014374'	System	01 Sep 2020 00:33:23
User entered 'No (N)'	System	01 Sep 2020 00:33:23

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:09', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1a01524e-8721-4dc2-bdfe-69cf86014374'	System	01 Sep 2020 00:33:23
User entered 'None (1)'	System	01 Sep 2020 00:33:23

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:16', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1a01524e-8721-4dc2-bdfe-69cf86014374'	System	01 Sep 2020 00:33:23
User entered '31 Aug 2020 20:33'	System	01 Sep 2020 00:33:23

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 5'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:00:59', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b746d89b-8726-418b-9f6a-b40d57775886'	System	02 Sep 2020 00:01:48
User entered 'None (1)'	System	02 Sep 2020 00:01:48

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:02', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b746d89b-8726-418b-9f6a-b40d57775886'	System	02 Sep 2020 00:01:48
User entered 'No (N)'	System	02 Sep 2020 00:01:48

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:05', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b746d89b-8726-418b-9f6a-b40d57775886'	System	02 Sep 2020 00:01:48
User entered 'No (N)'	System	02 Sep 2020 00:01:48

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:08', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b746d89b-8726-418b-9f6a-b40d57775886'	System	02 Sep 2020 00:01:48
User entered 'None (1)'	System	02 Sep 2020 00:01:48

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:10', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b746d89b-8726-418b-9f6a-b40d57775886'	System	02 Sep 2020 00:01:48
User entered '01 Sep 2020 20:01'	System	02 Sep 2020 00:01:48

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 6'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:01:37', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1f8cf26-ea8c-42e9-b680-9fd4f7a0bee9'	System	03 Sep 2020 01:01:54
User entered 'None (1)'	System	03 Sep 2020 01:01:54

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:01:40', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1f8cf26-ea8c-42e9-b680-9fd4f7a0bee9'	System	03 Sep 2020 01:01:54
User entered 'No (N)'	System	03 Sep 2020 01:01:54

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:01:43', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1f8cf26-ea8c-42e9-b680-9fd4f7a0bee9'	System	03 Sep 2020 01:01:54
User entered 'No (N)'	System	03 Sep 2020 01:01:54

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:01:46', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1f8cf26-ea8c-42e9-b680-9fd4f7a0bee9'	System	03 Sep 2020 01:01:54
User entered 'None (1)'	System	03 Sep 2020 01:01:54

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:01:52', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1f8cf26-ea8c-42e9-b680-9fd4f7a0bee9'	System	03 Sep 2020 01:01:54
User entered '02 Sep 2020 21:01'	System	03 Sep 2020 01:01:54

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 7'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:16', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '63eb9ce1-e5fe-4ea7-9949-19aa8b60fa93'	System	04 Sep 2020 03:01:45
User entered 'None (1)'	System	04 Sep 2020 03:01:45

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:19', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '63eb9ce1-e5fe-4ea7-9949-19aa8b60fa93'	System	04 Sep 2020 03:01:45
User entered 'No (N)'	System	04 Sep 2020 03:01:45

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:22', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '63eb9ce1-e5fe-4ea7-9949-19aa8b60fa93'	System	04 Sep 2020 03:01:45
User entered 'No (N)'	System	04 Sep 2020 03:01:45

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:25', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '63eb9ce1-e5fe-4ea7-9949-19aa8b60fa93'	System	04 Sep 2020 03:01:45
User entered 'None (1)'	System	04 Sep 2020 03:01:45

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:30', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '63eb9ce1-e5fe-4ea7-9949-19aa8b60fa93'	System	04 Sep 2020 03:01:45
User entered '03 Sep 2020 23:01'	System	04 Sep 2020 03:01:45

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:12', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '282b6def-78db-49e5-bdb2-a2f1e106dd3f'	System	28 Aug 2020 21:27:33
User entered 'None (0)'	System	28 Aug 2020 21:27:33

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:14', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '282b6def-78db-49e5-bdb2-a2f1e106dd3f'	System	28 Aug 2020 21:27:33
User entered 'None (0)'	System	28 Aug 2020 21:27:33

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:17', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '282b6def-78db-49e5-bdb2-a2f1e106dd3f'	System	28 Aug 2020 21:27:33
User entered 'None (0)'	System	28 Aug 2020 21:27:33

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:19', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '282b6def-78db-49e5-bdb2-a2f1e106dd3f'	System	28 Aug 2020 21:27:33
User entered 'None (0)'	System	28 Aug 2020 21:27:33

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:21', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '282b6def-78db-49e5-bdb2-a2f1e106dd3f'	System	28 Aug 2020 21:27:33
User entered 'None (0)'	System	28 Aug 2020 21:27:33

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:23', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '282b6def-78db-49e5-bdb2-a2f1e106dd3f'	System	28 Aug 2020 21:27:33
User entered 'None (0)'	System	28 Aug 2020 21:27:33

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:27', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '282b6def-78db-49e5-bdb2-a2f1e106dd3f'	System	28 Aug 2020 21:27:33
User entered 'No (N)'	System	28 Aug 2020 21:27:33

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T17:27:32', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '282b6def-78db-49e5-bdb2-a2f1e106dd3f'	System	28 Aug 2020 21:27:33
User entered '28 Aug 2020 17:27'	System	28 Aug 2020 21:27:33

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 17:06'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 19:36'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:45:05', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bed89a3a-9bdc-44d2-b778-a94bbcc09752'	System	29 Aug 2020 00:45:30
User entered 'None (0)'	System	29 Aug 2020 00:45:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:45:08', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bed89a3a-9bdc-44d2-b778-a94bbcc09752'	System	29 Aug 2020 00:45:30
User entered 'None (0)'	System	29 Aug 2020 00:45:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:45:10', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bed89a3a-9bdc-44d2-b778-a94bbcc09752'	System	29 Aug 2020 00:45:30
User entered 'None (0)'	System	29 Aug 2020 00:45:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:45:13', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bed89a3a-9bdc-44d2-b778-a94bbcc09752'	System	29 Aug 2020 00:45:30
User entered 'None (0)'	System	29 Aug 2020 00:45:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:45:15', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bed89a3a-9bdc-44d2-b778-a94bbcc09752'	System	29 Aug 2020 00:45:30
User entered 'None (0)'	System	29 Aug 2020 00:45:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:45:17', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bed89a3a-9bdc-44d2-b778-a94bbcc09752'	System	29 Aug 2020 00:45:30
User entered 'None (0)'	System	29 Aug 2020 00:45:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:45:20', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bed89a3a-9bdc-44d2-b778-a94bbcc09752'	System	29 Aug 2020 00:45:30
User entered 'No (N)'	System	29 Aug 2020 00:45:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-28T20:45:29', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bed89a3a-9bdc-44d2-b778-a94bbcc09752'	System	29 Aug 2020 00:45:30
User entered '28 Aug 2020 20:45'	System	29 Aug 2020 00:45:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 20:31'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 2'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:43:16', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '39722bda-82b7-4731-b5f8-5e625f228a29'	System	30 Aug 2020 01:43:40
User entered 'None (0)'	System	30 Aug 2020 01:43:40

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:43:19', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '39722bda-82b7-4731-b5f8-5e625f228a29'	System	30 Aug 2020 01:43:40
User entered 'None (0)'	System	30 Aug 2020 01:43:40

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:43:21', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '39722bda-82b7-4731-b5f8-5e625f228a29'	System	30 Aug 2020 01:43:40
User entered 'None (0)'	System	30 Aug 2020 01:43:40

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:43:24', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '39722bda-82b7-4731-b5f8-5e625f228a29'	System	30 Aug 2020 01:43:40
User entered 'None (0)'	System	30 Aug 2020 01:43:40

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:43:27', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '39722bda-82b7-4731-b5f8-5e625f228a29'	System	30 Aug 2020 01:43:40
User entered 'None (0)'	System	30 Aug 2020 01:43:40

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:43:29', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '39722bda-82b7-4731-b5f8-5e625f228a29'	System	30 Aug 2020 01:43:40
User entered 'None (0)'	System	30 Aug 2020 01:43:40

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:43:32', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '39722bda-82b7-4731-b5f8-5e625f228a29'	System	30 Aug 2020 01:43:40
User entered 'No (N)'	System	30 Aug 2020 01:43:40

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-29T21:43:36', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '39722bda-82b7-4731-b5f8-5e625f228a29'	System	30 Aug 2020 01:43:40
User entered '29 Aug 2020 21:43'	System	30 Aug 2020 01:43:40

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 3'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:14:56', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '69a9bb30-1f6e-42b5-b3ee-ba9dd923b3ca'	System	31 Aug 2020 00:16:25
User entered 'None (0)'	System	31 Aug 2020 00:16:25

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:14:59', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '69a9bb30-1f6e-42b5-b3ee-ba9dd923b3ca'	System	31 Aug 2020 00:16:25
User entered 'None (0)'	System	31 Aug 2020 00:16:25

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:15:02', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '69a9bb30-1f6e-42b5-b3ee-ba9dd923b3ca'	System	31 Aug 2020 00:16:25
User entered 'None (0)'	System	31 Aug 2020 00:16:25

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:15:05', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '69a9bb30-1f6e-42b5-b3ee-ba9dd923b3ca'	System	31 Aug 2020 00:16:25
User entered 'None (0)'	System	31 Aug 2020 00:16:25

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:15:08', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '69a9bb30-1f6e-42b5-b3ee-ba9dd923b3ca'	System	31 Aug 2020 00:16:25
User entered 'None (0)'	System	31 Aug 2020 00:16:25

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:15:10', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '69a9bb30-1f6e-42b5-b3ee-ba9dd923b3ca'	System	31 Aug 2020 00:16:25
User entered 'None (0)'	System	31 Aug 2020 00:16:25

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:15:18', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '69a9bb30-1f6e-42b5-b3ee-ba9dd923b3ca'	System	31 Aug 2020 00:16:25
User entered 'No (N)'	System	31 Aug 2020 00:16:25

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-30T20:15:21', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '69a9bb30-1f6e-42b5-b3ee-ba9dd923b3ca'	System	31 Aug 2020 00:16:25
User entered '30 Aug 2020 20:15'	System	31 Aug 2020 00:16:25

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 4'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:20', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'dcfd8e39-ba74-4310-827b-426f84cf84b4'	System	01 Sep 2020 00:33:45
User entered 'None (0)'	System	01 Sep 2020 00:33:45

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:23', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'dcfd8e39-ba74-4310-827b-426f84cf84b4'	System	01 Sep 2020 00:33:45
User entered 'None (0)'	System	01 Sep 2020 00:33:45

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:26', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'dcfd8e39-ba74-4310-827b-426f84cf84b4'	System	01 Sep 2020 00:33:45
User entered 'None (0)'	System	01 Sep 2020 00:33:45

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:28', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'dcfd8e39-ba74-4310-827b-426f84cf84b4'	System	01 Sep 2020 00:33:45
User entered 'None (0)'	System	01 Sep 2020 00:33:45

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:31', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'dcfd8e39-ba74-4310-827b-426f84cf84b4'	System	01 Sep 2020 00:33:45
User entered 'None (0)'	System	01 Sep 2020 00:33:45

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:33', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'dcfd8e39-ba74-4310-827b-426f84cf84b4'	System	01 Sep 2020 00:33:45
User entered 'None (0)'	System	01 Sep 2020 00:33:45

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:39', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'dcfd8e39-ba74-4310-827b-426f84cf84b4'	System	01 Sep 2020 00:33:45
User entered 'No (N)'	System	01 Sep 2020 00:33:45

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-08-31T20:33:42', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'dcfd8e39-ba74-4310-827b-426f84cf84b4'	System	01 Sep 2020 00:33:45
User entered '31 Aug 2020 20:33'	System	01 Sep 2020 00:33:45

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 5'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:14', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bc74fb95-e828-4243-a732-56742ac75d4c'	System	02 Sep 2020 00:02:17
User entered 'None (0)'	System	02 Sep 2020 00:02:17

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:17', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bc74fb95-e828-4243-a732-56742ac75d4c'	System	02 Sep 2020 00:02:17
User entered 'None (0)'	System	02 Sep 2020 00:02:17

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:21', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bc74fb95-e828-4243-a732-56742ac75d4c'	System	02 Sep 2020 00:02:17
User entered 'None (0)'	System	02 Sep 2020 00:02:17

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:24', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bc74fb95-e828-4243-a732-56742ac75d4c'	System	02 Sep 2020 00:02:17
User entered 'None (0)'	System	02 Sep 2020 00:02:17

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:27', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bc74fb95-e828-4243-a732-56742ac75d4c'	System	02 Sep 2020 00:02:17
User entered 'None (0)'	System	02 Sep 2020 00:02:17

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:29', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bc74fb95-e828-4243-a732-56742ac75d4c'	System	02 Sep 2020 00:02:17
User entered 'None (0)'	System	02 Sep 2020 00:02:17

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:32', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bc74fb95-e828-4243-a732-56742ac75d4c'	System	02 Sep 2020 00:02:17
User entered 'No (N)'	System	02 Sep 2020 00:02:17

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-01T20:01:39', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'bc74fb95-e828-4243-a732-56742ac75d4c'	System	02 Sep 2020 00:02:17
User entered '01 Sep 2020 20:01'	System	02 Sep 2020 00:02:17

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 6'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:01:56', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1ceb30e-e39d-4578-8cf5-d9b4e7196a69'	System	03 Sep 2020 01:02:30
User entered 'None (0)'	System	03 Sep 2020 01:02:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:01:58', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1ceb30e-e39d-4578-8cf5-d9b4e7196a69'	System	03 Sep 2020 01:02:30
User entered 'None (0)'	System	03 Sep 2020 01:02:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:02:01', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1ceb30e-e39d-4578-8cf5-d9b4e7196a69'	System	03 Sep 2020 01:02:30
User entered 'None (0)'	System	03 Sep 2020 01:02:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:02:03', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1ceb30e-e39d-4578-8cf5-d9b4e7196a69'	System	03 Sep 2020 01:02:30
User entered 'None (0)'	System	03 Sep 2020 01:02:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:02:05', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1ceb30e-e39d-4578-8cf5-d9b4e7196a69'	System	03 Sep 2020 01:02:30
User entered 'None (0)'	System	03 Sep 2020 01:02:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:02:07', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1ceb30e-e39d-4578-8cf5-d9b4e7196a69'	System	03 Sep 2020 01:02:30
User entered 'None (0)'	System	03 Sep 2020 01:02:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:02:12', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1ceb30e-e39d-4578-8cf5-d9b4e7196a69'	System	03 Sep 2020 01:02:30
User entered 'No (N)'	System	03 Sep 2020 01:02:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-02T21:02:25', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd1ceb30e-e39d-4578-8cf5-d9b4e7196a69'	System	03 Sep 2020 01:02:30
User entered '02 Sep 2020 21:02'	System	03 Sep 2020 01:02:30

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 7'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:35', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '675d475b-d07c-46b3-9999-880760634327'	System	04 Sep 2020 03:02:09
User entered 'None (0)'	System	04 Sep 2020 03:02:09

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:37', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '675d475b-d07c-46b3-9999-880760634327'	System	04 Sep 2020 03:02:09
User entered 'None (0)'	System	04 Sep 2020 03:02:09

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:39', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '675d475b-d07c-46b3-9999-880760634327'	System	04 Sep 2020 03:02:09
User entered 'None (0)'	System	04 Sep 2020 03:02:09

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:43', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '675d475b-d07c-46b3-9999-880760634327'	System	04 Sep 2020 03:02:09
User entered 'None (0)'	System	04 Sep 2020 03:02:09

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:45', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '675d475b-d07c-46b3-9999-880760634327'	System	04 Sep 2020 03:02:09
User entered 'None (0)'	System	04 Sep 2020 03:02:09

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:47', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '675d475b-d07c-46b3-9999-880760634327'	System	04 Sep 2020 03:02:09
User entered 'None (0)'	System	04 Sep 2020 03:02:09

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

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 (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:50', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '675d475b-d07c-46b3-9999-880760634327'	System	04 Sep 2020 03:02:09
User entered 'No (N)'	System	04 Sep 2020 03:02:09

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90D592E9-7180-49CD-A7E5-382A389309A3)', Time: '2020-09-03T23:01:57', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '675d475b-d07c-46b3-9999-880760634327'	System	04 Sep 2020 03:02:09
User entered '03 Sep 2020 23:01'	System	04 Sep 2020 03:02:09

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:25:10

US3632022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	11 Sep 2020 17:16:36
	(b) (4)	

US3632022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Bezuayehu Mandefro	11 Sep 2020 17:16:36
	(b) (4)	

US3632022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Bezuayehu Mandefro (b) (4)	11 Sep 2020 17:16:36

US3632022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	11 Sep 2020 17:16:36
	(b) (4)	

US3632022

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	11 Sep 2020 17:16:41
	(b) (4)	

US3632022

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:16:41

US3632022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	11 Sep 2020 17:17:07
	(b) (4)	

US3632022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Bezuayehu Mandefro	11 Sep 2020 17:17:07
	(b) (4)	

US3632022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Bezuayehu Mandefro (b) (4) 	11 Sep 2020 17:17:07

US3632022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	11 Sep 2020 17:17:07
	(b) (4)	

US3632022

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	11 Sep 2020 17:17:33
	(b) (4)	

US3632022

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:17:33

US3632022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	18 Sep 2020 16:08:34
	(b) (4)	

US3632022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Bezuayehu Mandefro	18 Sep 2020 16:08:34
	(b) (4)	

US3632022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Bezuayehu Mandefro (b) (4) 	18 Sep 2020 16:08:34

US3632022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	18 Sep 2020 16:08:34
	(b) (4)	

US3632022

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	18 Sep 2020 16:08:38
	(b) (4)	

US3632022

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:08:38

US3632022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Isaac Perez (b) (4) (b) (4)	25 Sep 2020 17:57:30

US3632022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Isaac Perez (b) (4) (b) (4)	25 Sep 2020 17:57:30

US3632022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Isaac Perez (b) (4) (b) (4)	25 Sep 2020 17:57:30

US3632022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	25 Sep 2020 17:57:30

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '12:04'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:04'	System	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '59'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 10:06:57
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Isaac Perez (b) (4)	28 Sep 2020 20:10:06
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	28 Sep 2020 17:36:31
User entered '57'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '14:33'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 14:33'	System	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 10:07:05
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Isaac Perez (b) (4)	28 Sep 2020 20:10:19
answered with 'NCS' (Site from System).	(b) (4)	
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Sep 2020 17:36:31
User entered '96.4' F	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '55'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '66'	(b) (4), (b) (6)	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 17:36:31

US3632022

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:34:45

US3632022

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 17:34:45

US3632022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Isaac Perez (b) (4) (b) (4)	25 Sep 2020 18:15:29

US3632022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Isaac Perez (b) (4) (b) (4)	25 Sep 2020 18:15:29

US3632022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	Isaac Perez (b) (4) (b) (4)	25 Sep 2020 18:15:29

US3632022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 18:15:29

US3632022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Isaac Perez (b) (4) (b) (4)	25 Sep 2020 18:15:29

US3632022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '14:01'	Isaac Perez (b) (4) (b) (4)	25 Sep 2020 18:15:29

US3632022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 14:01'	System	25 Sep 2020 18:15:29

US3632022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Isaac Perez (b) (4) (b) (4)	25 Sep 2020 18:15:29

US3632022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	25 Sep 2020 18:15:29

US3632022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 18:15:29

US3632022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:35:05

US3632022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 17:35:05

US3632022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:02'	(b) (4), (b) (6)	28 Sep 2020 17:35:05

US3632022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 13:02'	System	28 Sep 2020 17:35:05

US3632022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 17:35:15

US3632022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:22

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Sep 2020 17:35:15

US3632022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:35:15

US3632022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:05'	(b) (4), (b) (6)	28 Sep 2020 17:35:15

US3632022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 13:05'	System	28 Sep 2020 17:35:15

US3632022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:22

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Sep 2020 17:35:15

US3632022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 17:35:15

US3632022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 17:35:15

US3632022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 17:35:15

US3632022

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:34:37

US3632022

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 17:34:37

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:31:34', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '42402896-555b-4c2c-ba94-6b4d6d97b9b2'	System	25 Sep 2020 18:31:56
User entered 'Yes (Y)'	System	25 Sep 2020 18:31:56

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:31:41', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '42402896-555b-4c2c-ba94-6b4d6d97b9b2'	System	25 Sep 2020 18:31:56
User entered '96.4'	System	25 Sep 2020 18:31:56

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:31:45', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '42402896-555b-4c2c-ba94-6b4d6d97b9b2'	System	25 Sep 2020 18:31:56
User entered 'No (N)'	System	25 Sep 2020 18:31:56

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:31:52', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '42402896-555b-4c2c-ba94-6b4d6d97b9b2'	System	25 Sep 2020 18:31:56
User entered '25 Sep 2020 14:31'	System	25 Sep 2020 18:31:56

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 14:21'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 16:51'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:05', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'a9cb382d-e7ff-48f0-8809-0332f3af28ae'	System	26 Sep 2020 00:52:22
User entered 'Yes (Y)'	System	26 Sep 2020 00:52:22

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:12', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'a9cb382d-e7ff-48f0-8809-0332f3af28ae'	System	26 Sep 2020 00:52:22
User entered '96.8'	System	26 Sep 2020 00:52:22

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:15', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'a9cb382d-e7ff-48f0-8809-0332f3af28ae'	System	26 Sep 2020 00:52:22
User entered 'No (N)'	System	26 Sep 2020 00:52:22

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:19', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'a9cb382d-e7ff-48f0-8809-0332f3af28ae'	System	26 Sep 2020 00:52:22
User entered '25 Sep 2020 20:52'	System	26 Sep 2020 00:52:22

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 17:46'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 2'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:35:59', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f7b671e2-a649-4307-a748-3db0739de008'	System	26 Sep 2020 17:36:17
User entered 'Yes (Y)'	System	26 Sep 2020 17:36:17

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:06', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f7b671e2-a649-4307-a748-3db0739de008' User entered '97.8'	System	26 Sep 2020 17:36:17

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:09', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f7b671e2-a649-4307-a748-3db0739de008'	System	26 Sep 2020 17:36:17
User entered 'No (N)'	System	26 Sep 2020 17:36:17

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:13', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f7b671e2-a649-4307-a748-3db0739de008'	System	26 Sep 2020 17:36:17
User entered '26 Sep 2020 13:36'	System	26 Sep 2020 17:36:17

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 3'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:08:42', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9771eb78-96e5-46b8-9109-8f2be9d8b6c5'	System	27 Sep 2020 16:08:59
User entered 'Yes (Y)'	System	27 Sep 2020 16:08:59

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:08:49', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9771eb78-96e5-46b8-9109-8f2be9d8b6c5'	System	27 Sep 2020 16:08:59
User entered '97.2'	System	27 Sep 2020 16:08:59

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:08:52', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9771eb78-96e5-46b8-9109-8f2be9d8b6c5'	System	27 Sep 2020 16:08:59
User entered 'No (N)'	System	27 Sep 2020 16:08:59

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:08:58', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9771eb78-96e5-46b8-9109-8f2be9d8b6c5'	System	27 Sep 2020 16:08:59
User entered '27 Sep 2020 12:08'	System	27 Sep 2020 16:08:59

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 4'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:42:58', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9af1b19a-e519-4cca-b194-90b8c505c15e'	System	28 Sep 2020 16:43:13
User entered 'Yes (Y)'	System	28 Sep 2020 16:43:13

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:04', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9af1b19a-e519-4cca-b194-90b8c505c15e'	System	28 Sep 2020 16:43:13
User entered '96.8'	System	28 Sep 2020 16:43:13

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:07', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9af1b19a-e519-4cca-b194-90b8c505c15e'	System	28 Sep 2020 16:43:13
User entered 'No (N)'	System	28 Sep 2020 16:43:13

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:09', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9af1b19a-e519-4cca-b194-90b8c505c15e'	System	28 Sep 2020 16:43:13
User entered '28 Sep 2020 12:43'	System	28 Sep 2020 16:43:13

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 5'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:37:18', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '553181bf-d3cb-4a51-9b20-16892dcb8b66'	System	29 Sep 2020 16:37:37
User entered 'Yes (Y)'	System	29 Sep 2020 16:37:37

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:37:25', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '553181bf-d3cb-4a51-9b20-16892dcb8b66'	System	29 Sep 2020 16:37:37
User entered '98.1'	System	29 Sep 2020 16:37:37

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:37:30', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '553181bf-d3cb-4a51-9b20-16892dcb8b66'	System	29 Sep 2020 16:37:37
User entered 'No (N)'	System	29 Sep 2020 16:37:37

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:37:33', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '553181bf-d3cb-4a51-9b20-16892dcb8b66'	System	29 Sep 2020 16:37:37
User entered '29 Sep 2020 12:37'	System	29 Sep 2020 16:37:37

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 6'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:00', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'ed6d9d11-84b7-4492-b1a7-c225d5dc2c99'	System	30 Sep 2020 18:16:19
User entered 'Yes (Y)'	System	30 Sep 2020 18:16:19

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:08', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'ed6d9d11-84b7-4492-b1a7-c225d5dc2c99'	System	30 Sep 2020 18:16:19
User entered '97.8'	System	30 Sep 2020 18:16:19

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:11', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'ed6d9d11-84b7-4492-b1a7-c225d5dc2c99'	System	30 Sep 2020 18:16:19
User entered 'No (N)'	System	30 Sep 2020 18:16:19

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:15', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'ed6d9d11-84b7-4492-b1a7-c225d5dc2c99'	System	30 Sep 2020 18:16:19
User entered '30 Sep 2020 14:16'	System	30 Sep 2020 18:16:19

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 7'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:00:47', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '0c936119-7bdb-4ed3-b27f-1718b7188dbb'	System	01 Oct 2020 16:01:19
User entered 'Yes (Y)'	System	01 Oct 2020 16:01:19

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:00:53', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '0c936119-7bdb-4ed3-b27f-1718b7188dbb'	System	01 Oct 2020 16:01:19
User entered '97.2'	System	01 Oct 2020 16:01:19

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:00:55', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '0c936119-7bdb-4ed3-b27f-1718b7188dbb'	System	01 Oct 2020 16:01:19
User entered 'No (N)'	System	01 Oct 2020 16:01:19

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:00:59', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '0c936119-7bdb-4ed3-b27f-1718b7188dbb'	System	01 Oct 2020 16:01:19
User entered '01 Oct 2020 12:00'	System	01 Oct 2020 16:01:19

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:00', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2bea4c8e-cc6f-42a4-833d-ae327df1dcd1'	System	25 Sep 2020 18:32:17
User entered 'None (1)'	System	25 Sep 2020 18:32:17

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:04', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2bea4c8e-cc6f-42a4-833d-ae327df1dcd1'	System	25 Sep 2020 18:32:17
User entered 'No (N)'	System	25 Sep 2020 18:32:17

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:08', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2bea4c8e-cc6f-42a4-833d-ae327df1dcd1'	System	25 Sep 2020 18:32:17
User entered 'No (N)'	System	25 Sep 2020 18:32:17

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:11', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2bea4c8e-cc6f-42a4-833d-ae327df1dcd1'	System	25 Sep 2020 18:32:17
User entered 'None (1)'	System	25 Sep 2020 18:32:17

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:14', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2bea4c8e-cc6f-42a4-833d-ae327df1dcd1'	System	25 Sep 2020 18:32:17
User entered '25 Sep 2020 14:32'	System	25 Sep 2020 18:32:17

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 14:21'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 16:51'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:25', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9b5624e9-8e65-4d33-9d3f-5ee457f00689'	System	26 Sep 2020 00:52:44
User entered 'None (1)'	System	26 Sep 2020 00:52:44

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:29', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9b5624e9-8e65-4d33-9d3f-5ee457f00689'	System	26 Sep 2020 00:52:44
User entered 'No (N)'	System	26 Sep 2020 00:52:44

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:32', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9b5624e9-8e65-4d33-9d3f-5ee457f00689'	System	26 Sep 2020 00:52:44
User entered 'No (N)'	System	26 Sep 2020 00:52:44

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:35', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9b5624e9-8e65-4d33-9d3f-5ee457f00689'	System	26 Sep 2020 00:52:44
User entered 'None (1)'	System	26 Sep 2020 00:52:44

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:42', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '9b5624e9-8e65-4d33-9d3f-5ee457f00689'	System	26 Sep 2020 00:52:44
User entered '25 Sep 2020 20:52'	System	26 Sep 2020 00:52:44

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 17:46'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 2'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:17', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2e47e9e5-f597-4489-927f-42a8b29f9c5a'	System	26 Sep 2020 17:36:32
User entered 'None (1)'	System	26 Sep 2020 17:36:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:20', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2e47e9e5-f597-4489-927f-42a8b29f9c5a'	System	26 Sep 2020 17:36:32
User entered 'No (N)'	System	26 Sep 2020 17:36:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:22', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2e47e9e5-f597-4489-927f-42a8b29f9c5a'	System	26 Sep 2020 17:36:32
User entered 'No (N)'	System	26 Sep 2020 17:36:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:25', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2e47e9e5-f597-4489-927f-42a8b29f9c5a'	System	26 Sep 2020 17:36:32
User entered 'None (1)'	System	26 Sep 2020 17:36:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:28', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '2e47e9e5-f597-4489-927f-42a8b29f9c5a'	System	26 Sep 2020 17:36:32
User entered '26 Sep 2020 13:36'	System	26 Sep 2020 17:36:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 3'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:08', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'a88cf003-bf21-45aa-98b2-e3567fb1e122'	System	27 Sep 2020 16:09:22
User entered 'None (1)'	System	27 Sep 2020 16:09:22

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:11', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'a88cf003-bf21-45aa-98b2-e3567fb1e122'	System	27 Sep 2020 16:09:22
User entered 'No (N)'	System	27 Sep 2020 16:09:22

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:14', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'a88cf003-bf21-45aa-98b2-e3567fb1e122'	System	27 Sep 2020 16:09:22
User entered 'No (N)'	System	27 Sep 2020 16:09:22

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:16', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'a88cf003-bf21-45aa-98b2-e3567fb1e122'	System	27 Sep 2020 16:09:22
User entered 'None (1)'	System	27 Sep 2020 16:09:22

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:21', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'a88cf003-bf21-45aa-98b2-e3567fb1e122'	System	27 Sep 2020 16:09:22
User entered '27 Sep 2020 12:09'	System	27 Sep 2020 16:09:22

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 4'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:13', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b357defb-e32e-4212-8378-a568af16e80c'	System	28 Sep 2020 16:43:33
User entered 'None (1)'	System	28 Sep 2020 16:43:33

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:16', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b357defb-e32e-4212-8378-a568af16e80c'	System	28 Sep 2020 16:43:33
User entered 'No (N)'	System	28 Sep 2020 16:43:33

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:20', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b357defb-e32e-4212-8378-a568af16e80c'	System	28 Sep 2020 16:43:33
User entered 'No (N)'	System	28 Sep 2020 16:43:33

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:25', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b357defb-e32e-4212-8378-a568af16e80c'	System	28 Sep 2020 16:43:33
User entered 'None (1)'	System	28 Sep 2020 16:43:33

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:30', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'b357defb-e32e-4212-8378-a568af16e80c'	System	28 Sep 2020 16:43:33
User entered '28 Sep 2020 12:43'	System	28 Sep 2020 16:43:33

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 5'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:37:38', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '990ffcb7-0245-4134-a185-de527439cdcb' User entered 'None (1)'	System	29 Sep 2020 16:37:53
	System	29 Sep 2020 16:37:53

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:37:41', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '990ffcb7-0245-4134-a185-de527439cdcb'	System	29 Sep 2020 16:37:53
User entered 'No (N)'	System	29 Sep 2020 16:37:53

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:37:45', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '990ffcb7-0245-4134-a185-de527439cdcb' User entered 'No (N)'	System	29 Sep 2020 16:37:53

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:37:49', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '990ffcb7-0245-4134-a185-de527439cdcb' User entered 'None (1)'	System	29 Sep 2020 16:37:53
	System	29 Sep 2020 16:37:53

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:37:52', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '990ffcb7-0245-4134-a185-de527439cdcb' User entered '29 Sep 2020 12:37'	System	29 Sep 2020 16:37:53
	System	29 Sep 2020 16:37:53

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 6'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:19', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '3249573e-4bd7-499b-9d87-bd72bfb480e2'	System	30 Sep 2020 18:16:32
User entered 'None (1)'	System	30 Sep 2020 18:16:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:21', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '3249573e-4bd7-499b-9d87-bd72bfb480e2'	System	30 Sep 2020 18:16:32
User entered 'No (N)'	System	30 Sep 2020 18:16:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:24', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '3249573e-4bd7-499b-9d87-bd72bfb480e2'	System	30 Sep 2020 18:16:32
User entered 'No (N)'	System	30 Sep 2020 18:16:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:26', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '3249573e-4bd7-499b-9d87-bd72bfb480e2'	System	30 Sep 2020 18:16:32
User entered 'None (1)'	System	30 Sep 2020 18:16:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:29', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '3249573e-4bd7-499b-9d87-bd72bfb480e2'	System	30 Sep 2020 18:16:32
User entered '30 Sep 2020 14:16'	System	30 Sep 2020 18:16:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 7'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:02', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '175354ab-ba41-41a8-bdc8-4635e9e7f8ae'	System	01 Oct 2020 16:01:32
User entered 'None (1)'	System	01 Oct 2020 16:01:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:06', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '175354ab-ba41-41a8-bdc8-4635e9e7f8ae'	System	01 Oct 2020 16:01:32
User entered 'No (N)'	System	01 Oct 2020 16:01:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:08', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '175354ab-ba41-41a8-bdc8-4635e9e7f8ae' User entered 'No (N)'	System	01 Oct 2020 16:01:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:10', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '175354ab-ba41-41a8-bdc8-4635e9e7f8ae' User entered 'None (1)'	System	01 Oct 2020 16:01:32
	System	01 Oct 2020 16:01:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:14', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '175354ab-ba41-41a8-bdc8-4635e9e7f8ae' User entered '01 Oct 2020 12:01'	System	01 Oct 2020 16:01:32
	System	01 Oct 2020 16:01:32

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:18', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '333f645c-b424-49d5-a302-febb9fd20739'	System	25 Sep 2020 18:32:37
User entered 'None (0)'	System	25 Sep 2020 18:32:37

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:21', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '333f645c-b424-49d5-a302-febb9fd20739'	System	25 Sep 2020 18:32:37
User entered 'None (0)'	System	25 Sep 2020 18:32:37

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:23', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '333f645c-b424-49d5-a302-febb9fd20739'	System	25 Sep 2020 18:32:37
User entered 'None (0)'	System	25 Sep 2020 18:32:37

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:25', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '333f645c-b424-49d5-a302-febb9fd20739'	System	25 Sep 2020 18:32:37
User entered 'None (0)'	System	25 Sep 2020 18:32:37

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:28', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '333f645c-b424-49d5-a302-febb9fd20739'	System	25 Sep 2020 18:32:37
User entered 'None (0)'	System	25 Sep 2020 18:32:37

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:30', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '333f645c-b424-49d5-a302-febb9fd20739'	System	25 Sep 2020 18:32:37
User entered 'None (0)'	System	25 Sep 2020 18:32:37

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:33', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '333f645c-b424-49d5-a302-febb9fd20739'	System	25 Sep 2020 18:32:37
User entered 'No (N)'	System	25 Sep 2020 18:32:37

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T14:32:36', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '333f645c-b424-49d5-a302-febb9fd20739' User entered '25 Sep 2020 14:32'	System	25 Sep 2020 18:32:37
	System	25 Sep 2020 18:32:37

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 14:21'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 16:51'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:45', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd8841fac-d69e-4765-8bf6-8b55f910e965'	System	26 Sep 2020 00:53:06
User entered 'None (0)'	System	26 Sep 2020 00:53:06

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:47', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd8841fac-d69e-4765-8bf6-8b55f910e965'	System	26 Sep 2020 00:53:06
User entered 'None (0)'	System	26 Sep 2020 00:53:06

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:49', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd8841fac-d69e-4765-8bf6-8b55f910e965'	System	26 Sep 2020 00:53:06
User entered 'None (0)'	System	26 Sep 2020 00:53:06

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:51', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd8841fac-d69e-4765-8bf6-8b55f910e965'	System	26 Sep 2020 00:53:06
User entered 'None (0)'	System	26 Sep 2020 00:53:06

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:53', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd8841fac-d69e-4765-8bf6-8b55f910e965'	System	26 Sep 2020 00:53:06
User entered 'None (0)'	System	26 Sep 2020 00:53:06

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:54', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd8841fac-d69e-4765-8bf6-8b55f910e965'	System	26 Sep 2020 00:53:06
User entered 'None (0)'	System	26 Sep 2020 00:53:06

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:52:59', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd8841fac-d69e-4765-8bf6-8b55f910e965'	System	26 Sep 2020 00:53:06
User entered 'No (N)'	System	26 Sep 2020 00:53:06

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-25T20:53:02', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd8841fac-d69e-4765-8bf6-8b55f910e965'	System	26 Sep 2020 00:53:06
User entered '25 Sep 2020 20:53'	System	26 Sep 2020 00:53:06

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 17:46'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 2'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:31', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '92c09a4a-0744-47e7-8fa4-213eafccf6c6'	System	26 Sep 2020 17:36:50
User entered 'None (0)'	System	26 Sep 2020 17:36:50

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:33', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '92c09a4a-0744-47e7-8fa4-213eafccf6c6'	System	26 Sep 2020 17:36:50
User entered 'None (0)'	System	26 Sep 2020 17:36:50

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:35', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '92c09a4a-0744-47e7-8fa4-213eafccf6c6'	System	26 Sep 2020 17:36:50
User entered 'None (0)'	System	26 Sep 2020 17:36:50

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:36', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '92c09a4a-0744-47e7-8fa4-213eafccf6c6'	System	26 Sep 2020 17:36:50
User entered 'None (0)'	System	26 Sep 2020 17:36:50

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:38', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '92c09a4a-0744-47e7-8fa4-213eafccf6c6'	System	26 Sep 2020 17:36:50
User entered 'None (0)'	System	26 Sep 2020 17:36:50

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:40', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '92c09a4a-0744-47e7-8fa4-213eafccf6c6'	System	26 Sep 2020 17:36:50
User entered 'None (0)'	System	26 Sep 2020 17:36:50

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:43', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '92c09a4a-0744-47e7-8fa4-213eafccf6c6'	System	26 Sep 2020 17:36:50
User entered 'No (N)'	System	26 Sep 2020 17:36:50

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-26T13:36:48', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '92c09a4a-0744-47e7-8fa4-213eafccf6c6'	System	26 Sep 2020 17:36:50
User entered '26 Sep 2020 13:36'	System	26 Sep 2020 17:36:50

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 3'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:24', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd0d8f153-843e-41ec-8f22-6e84494fcad2'	System	27 Sep 2020 16:09:44
User entered 'None (0)'	System	27 Sep 2020 16:09:44

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:26', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd0d8f153-843e-41ec-8f22-6e84494fcad2'	System	27 Sep 2020 16:09:44
User entered 'None (0)'	System	27 Sep 2020 16:09:44

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:28', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd0d8f153-843e-41ec-8f22-6e84494fcad2'	System	27 Sep 2020 16:09:44
User entered 'None (0)'	System	27 Sep 2020 16:09:44

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:30', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd0d8f153-843e-41ec-8f22-6e84494fcad2'	System	27 Sep 2020 16:09:44
User entered 'None (0)'	System	27 Sep 2020 16:09:44

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:32', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd0d8f153-843e-41ec-8f22-6e84494fcad2'	System	27 Sep 2020 16:09:44
User entered 'None (0)'	System	27 Sep 2020 16:09:44

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:33', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd0d8f153-843e-41ec-8f22-6e84494fcad2'	System	27 Sep 2020 16:09:44
User entered 'None (0)'	System	27 Sep 2020 16:09:44

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:36', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd0d8f153-843e-41ec-8f22-6e84494fcad2'	System	27 Sep 2020 16:09:44
User entered 'No (N)'	System	27 Sep 2020 16:09:44

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-27T12:09:42', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd0d8f153-843e-41ec-8f22-6e84494fcad2'	System	27 Sep 2020 16:09:44
User entered '27 Sep 2020 12:09'	System	27 Sep 2020 16:09:44

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 4'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:34', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd925e3ee-66db-4587-9bab-7d91e859a6ac'	System	28 Sep 2020 16:43:51
User entered 'None (0)'	System	28 Sep 2020 16:43:51

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:35', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd925e3ee-66db-4587-9bab-7d91e859a6ac'	System	28 Sep 2020 16:43:51
User entered 'None (0)'	System	28 Sep 2020 16:43:51

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:37', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd925e3ee-66db-4587-9bab-7d91e859a6ac'	System	28 Sep 2020 16:43:51
User entered 'None (0)'	System	28 Sep 2020 16:43:51

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:39', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd925e3ee-66db-4587-9bab-7d91e859a6ac'	System	28 Sep 2020 16:43:51
User entered 'None (0)'	System	28 Sep 2020 16:43:51

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:41', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd925e3ee-66db-4587-9bab-7d91e859a6ac'	System	28 Sep 2020 16:43:51
User entered 'None (0)'	System	28 Sep 2020 16:43:51

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:43', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd925e3ee-66db-4587-9bab-7d91e859a6ac'	System	28 Sep 2020 16:43:51
User entered 'None (0)'	System	28 Sep 2020 16:43:51

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:45', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd925e3ee-66db-4587-9bab-7d91e859a6ac'	System	28 Sep 2020 16:43:51
User entered 'No (N)'	System	28 Sep 2020 16:43:51

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-28T12:43:48', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'd925e3ee-66db-4587-9bab-7d91e859a6ac'	System	28 Sep 2020 16:43:51
User entered '28 Sep 2020 12:43'	System	28 Sep 2020 16:43:51

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 5'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:38:12', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '958dd342-8bb7-4cf7-866c-ada7f0beb903'	System	29 Sep 2020 16:38:43
User entered 'None (0)'	System	29 Sep 2020 16:38:43

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:38:14', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '958dd342-8bb7-4cf7-866c-ada7f0beb903'	System	29 Sep 2020 16:38:43
User entered 'None (0)'	System	29 Sep 2020 16:38:43

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:38:18', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '958dd342-8bb7-4cf7-866c-ada7f0beb903'	System	29 Sep 2020 16:38:43
User entered 'None (0)'	System	29 Sep 2020 16:38:43

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:38:24', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '958dd342-8bb7-4cf7-866c-ada7f0beb903'	System	29 Sep 2020 16:38:43
User entered 'None (0)'	System	29 Sep 2020 16:38:43

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:38:26', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '958dd342-8bb7-4cf7-866c-ada7f0beb903'	System	29 Sep 2020 16:38:43
User entered 'None (0)'	System	29 Sep 2020 16:38:43

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:38:29', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '958dd342-8bb7-4cf7-866c-ada7f0beb903'	System	29 Sep 2020 16:38:43
User entered 'None (0)'	System	29 Sep 2020 16:38:43

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:38:35', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '958dd342-8bb7-4cf7-866c-ada7f0beb903'	System	29 Sep 2020 16:38:43
User entered 'No (N)'	System	29 Sep 2020 16:38:43

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-29T12:38:38', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '958dd342-8bb7-4cf7-866c-ada7f0beb903'	System	29 Sep 2020 16:38:43
User entered '29 Sep 2020 12:38'	System	29 Sep 2020 16:38:43

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 6'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:32', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f59a4084-82d7-4b83-92ed-53e11fcf9d7d'	System	30 Sep 2020 18:16:53
User entered 'None (0)'	System	30 Sep 2020 18:16:53

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:34', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f59a4084-82d7-4b83-92ed-53e11fcf9d7d'	System	30 Sep 2020 18:16:53
User entered 'None (0)'	System	30 Sep 2020 18:16:53

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:36', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f59a4084-82d7-4b83-92ed-53e11fcf9d7d'	System	30 Sep 2020 18:16:53
User entered 'None (0)'	System	30 Sep 2020 18:16:53

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:38', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f59a4084-82d7-4b83-92ed-53e11fcf9d7d'	System	30 Sep 2020 18:16:53
User entered 'None (0)'	System	30 Sep 2020 18:16:53

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:40', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f59a4084-82d7-4b83-92ed-53e11fcf9d7d'	System	30 Sep 2020 18:16:53
User entered 'None (0)'	System	30 Sep 2020 18:16:53

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:42', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f59a4084-82d7-4b83-92ed-53e11fcf9d7d'	System	30 Sep 2020 18:16:53
User entered 'None (0)'	System	30 Sep 2020 18:16:53

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:45', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f59a4084-82d7-4b83-92ed-53e11fcf9d7d'	System	30 Sep 2020 18:16:53
User entered 'No (N)'	System	30 Sep 2020 18:16:53

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-09-30T14:16:47', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'f59a4084-82d7-4b83-92ed-53e11fcf9d7d'	System	30 Sep 2020 18:16:53
User entered '30 Sep 2020 14:16'	System	30 Sep 2020 18:16:53

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 18:15:29
User entered 'Day 7'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:18', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1e642b5d-ab42-41a8-b95d-0e4ae499f426'	System	01 Oct 2020 16:01:58
User entered 'None (0)'	System	01 Oct 2020 16:01:58

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:19', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1e642b5d-ab42-41a8-b95d-0e4ae499f426'	System	01 Oct 2020 16:01:58
User entered 'None (0)'	System	01 Oct 2020 16:01:58

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:21', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1e642b5d-ab42-41a8-b95d-0e4ae499f426'	System	01 Oct 2020 16:01:58
User entered 'None (0)'	System	01 Oct 2020 16:01:58

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:23', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1e642b5d-ab42-41a8-b95d-0e4ae499f426'	System	01 Oct 2020 16:01:58
User entered 'None (0)'	System	01 Oct 2020 16:01:58

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:24', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1e642b5d-ab42-41a8-b95d-0e4ae499f426'	System	01 Oct 2020 16:01:58
User entered 'None (0)'	System	01 Oct 2020 16:01:58

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:26', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1e642b5d-ab42-41a8-b95d-0e4ae499f426'	System	01 Oct 2020 16:01:58
User entered 'None (0)'	System	01 Oct 2020 16:01:58

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:29', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1e642b5d-ab42-41a8-b95d-0e4ae499f426'	System	01 Oct 2020 16:01:58
User entered 'No (N)'	System	01 Oct 2020 16:01:58

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-01T12:01:34', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '1e642b5d-ab42-41a8-b95d-0e4ae499f426'	System	01 Oct 2020 16:01:58
User entered '01 Oct 2020 12:01'	System	01 Oct 2020 16:01:58

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 18:15:29

US3632022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 18:15:29

US3632022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christina Bacher (b) (4)	09 Oct 2020 16:02:15
	(b) (4)	

US3632022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Oct 2020 16:02:33
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	09 Oct 2020 16:02:33
User entered '2 Oct 2020' reason for change: Data Entry Error	Christina Bacher (b) (4)	09 Oct 2020 16:02:33
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Oct 2020 16:02:15
User entered '9 Oct 2020'	Christina Bacher (b) (4)	09 Oct 2020 16:02:15

US3632022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Christina Bacher (b) (4)	09 Oct 2020 16:02:15

US3632022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	09 Oct 2020 16:02:15

US3632022

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	09 Oct 2020 16:02:37

US3632022

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 16:02:37

US3632022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christina Bacher (b) (4)	09 Oct 2020 16:02:47
	(b) (4)	

US3632022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	Christina Bacher (b) (4) (b) (4)	09 Oct 2020 16:02:47

US3632022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Christina Bacher (b) (4)	09 Oct 2020 16:02:47

US3632022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4)	09 Oct 2020 16:02:47
	(b) (4)	

US3632022

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	09 Oct 2020 16:02:51

US3632022

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 16:02:51

US3632022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:16:58

US3632022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:16:58

US3632022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:16:58

US3632022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:16:58

US3632022

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	16 Oct 2020 14:17:04

US3632022

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:17:04

US3632022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 14:17:44

US3632022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 14:17:44

US3632022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Oct 2020 14:17:44

US3632022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	29 Oct 2020 14:17:44

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 14:17:55

US3632022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 14:18:00

US3632022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 14:18:00

US3632022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 14:18:18

US3632022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 14:18:18

US3632022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '10:16'	(b) (4), (b) (6)	29 Oct 2020 14:18:18

US3632022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '29 Oct 2020 10:16'	System	29 Oct 2020 14:18:18

US3632022

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 14:19:16

US3632022

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:19:16

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 64'	System	28 Aug 2020 21:25:10

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-29T12:15:32', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '96dba0b4-1220-4caf-a2c8-2c85d0f7ecc1'	System	29 Oct 2020 16:15:49
User entered 'No (N)'	System	29 Oct 2020 16:15:49

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

Have you been exposed to someone with 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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-29T12:15:37', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '96dba0b4-1220-4caf-a2c8-2c85d0f7ecc1'	System	29 Oct 2020 16:15:49
User entered 'No (N)'	System	29 Oct 2020 16:15:49

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-10-29T12:15:45', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '96dba0b4-1220-4caf-a2c8-2c85d0f7ecc1' User entered '29 Oct 2020 12:15:45'	System	29 Oct 2020 16:15:49
	System	29 Oct 2020 16:15:49

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 21:25:10

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 71'	System	28 Aug 2020 21:25:10

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-04T14:18:43', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '5888fbb9-b5bb-4a2e-95c9-5c230233675a' User entered 'No (N)'	System	04 Nov 2020 19:18:54

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

Have you been exposed to someone with 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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-04T14:18:46', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '5888fbb9-b5bb-4a2e-95c9-5c230233675a'	System	04 Nov 2020 19:18:54
User entered 'No (N)'	System	04 Nov 2020 19:18:54

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-04T14:18:52', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: '5888fbb9-b5bb-4a2e-95c9-5c230233675a' User entered '04 Nov 2020 14:18:52'	System	04 Nov 2020 19:18:54
	System	04 Nov 2020 19:18:54

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 21:25:10

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered 'Day 78'	System	28 Aug 2020 21:25:10

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-13T12:00:53', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'cbbdd979-8967-4832-bc4f-879cfb32f496'	System	13 Nov 2020 20:01:10
User entered 'No (N)'	System	13 Nov 2020 20:01:10

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

Have you been exposed to someone with 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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-13T12:00:56', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'cbbdd979-8967-4832-bc4f-879cfb32f496'	System	13 Nov 2020 20:01:10
User entered 'No (N)'	System	13 Nov 2020 20:01:10

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-13T12:01:01', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'cbbdd979-8967-4832-bc4f-879cfb32f496'	System	13 Nov 2020 20:01:10
User entered '13 Nov 2020 12:01:01'	System	13 Nov 2020 20:01:10

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 21:25:10

US3632022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:25:10
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 21:25:10

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-23T09:34:19', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'c6b53014-c422-470d-8fb9-e46abdf03c7'	System	23 Nov 2020 14:35:08
User entered 'Yes (Y)'	System	23 Nov 2020 14:35:08

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

Have you been exposed to someone with 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 (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-23T09:34:23', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'c6b53014-c422-470d-8fb9-e46abdf03c7'	System	23 Nov 2020 14:35:08
User entered 'No (N)'	System	23 Nov 2020 14:35:08

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-23T09:34:26', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'c6b53014-c422-470d-8fb9-e46abdf03c7'	System	23 Nov 2020 14:35:08
User entered 'No (N)'	System	23 Nov 2020 14:35:08

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-23T09:34:36', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'c6b53014-c422-470d-8fb9-e46abdf03c7'	System	23 Nov 2020 14:35:08
User entered 'Yes (Y)'	System	23 Nov 2020 14:35:08

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-23T09:34:50', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'c6b53014-c422-470d-8fb9-e46abdf03c7'	System	23 Nov 2020 14:35:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Nov 2020 14:35:08

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B593D14A-B06E-4E03-8A17-B13742CC3E07)', Time: '2020-11-23T09:34:56', User OID: 'PatientReportedOutcome (US3632022)', ODM File OID: 'c6b53014-c422-470d-8fb9-e46abdf03c7'	System	23 Nov 2020 14:35:08
User entered '23 Nov 2020 09:34:56'	System	23 Nov 2020 14:35:08

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 20:07:26

US3632022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:07:26
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 20:07:26

US3632022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	20 Nov 2020 14:27:23

US3632022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	20 Nov 2020 14:27:23

US3632022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4) (b) (4)	20 Nov 2020 14:27:23

US3632022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	20 Nov 2020 14:27:23

US3632022

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	20 Nov 2020 14:27:27

US3632022

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 14:27:27

US3632022

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:22

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:26:46

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:46:58
User entered 'USA-US120-2020-mRNA-1273-P301000006'	System	24 Nov 2020 13:46:54
User entered 'New'	(b) (4), (b) (6)	24 Nov 2020 13:46:54

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Soft tissue neoplasms malignant and unspecified, HLT: Leiomyosarcomas, PT: Leiomyosarcoma metastatic, LLT: Leiomyosarcoma metastatic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 22:35:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 22:35:07
Data point term sent to Coder	System	23 Nov 2020 16:29:21
User entered 'Metastatic leiomyosarcoma'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Life threatening](#)

Audit	User	Time (GMT)
User entered '1'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Nov 2020 16:30:40
User entered '1' reason for change: Data Entry Error	Christina Bacher (b) (4)	23 Nov 2020 16:30:40
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Nov 2020 16:29:02
User entered '0'	Christina Bacher (b) (4)	23 Nov 2020 16:29:02
	(b) (4)	

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant was initially diagnosed with leiomyosarcoma in 2017. During routine imaging, she was found to have metastatic disease to her liver. She is currently asymptomatic.'	Christina Bacher (b) (4)	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 16:29:02

US3632022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 16:29:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:22

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 17:02:07

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 17:04:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 17:04:47
Data point term sent to Coder	System	02 Sep 2020 17:03:59
User entered 'Zolpidem'	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 17:05:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 17:05:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:05:51
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 17:03:20
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'Insomnia'	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 UNK 2017'	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 17:05:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 17:05:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:05:51
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 17:03:20
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:03:20

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 17:05:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 17:05:45
Data point term sent to Coder	System	02 Sep 2020 17:05:00
User entered 'Lexapro'	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'Anxiety'	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 UNK 2017'	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 17:04:13

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CARBONATE;ERGOCALCIFEROL, PRODUCTSYNONYM: CALCIUM AND VITAMIN D - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:06:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:06:49
Data point term sent to Coder	System	02 Sep 2020 17:06:02
User entered 'Calcium and Vitamin D'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of OSTEOPOROSIS. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:32:31
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of OSTEOPOROSIS. Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'Participant was taking it for osteopenia before osteoporosis ' (Site from DM).	Bezuayehu Mandefro (b) (4)	27 Oct 2020 19:51:32
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of OSTEOPOROSIS. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 08:56:39
User entered 'Osteoporosis'	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '600/400IU' reason for change: Data Entry Error	Bezuayehu Mandefro (b) (4)	27 Oct 2020 19:55:32
User entered '600'	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 20:36:57
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components.' answered with 'updated' (Site from DM).	Bezuayehu Mandefro (b) (4)	27 Oct 2020 19:55:44
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 08:56:37
User entered '1 UNK 2010'	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 17:06:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 17:06:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:06:11
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 17:05:02
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 17:05:02

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[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)	02 Sep 2020 17:07:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 17:07:13
Data point term sent to Coder	System	02 Sep 2020 17:06:03
User entered 'Multivitamin'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'General Health'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unknown'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'unknown'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

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

Audit	User	Time (GMT)
User entered '1 UNK 2010'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 17:05:38

US3632022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:09:22

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 17:06:26

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'USA-US120-2020-MRNA-1273-P301000006'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'Yes (Y)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'No (N)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'Yes (Y)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'No (N)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'No (N)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'No (N)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'No (N)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'Colleen'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'Kelley'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'GA'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	24 Nov 2020 13:47:21

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 13:47:21

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'USA-US120-2020-MRNA-1273-P301000006'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'Yes (Y)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'No (N)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'Yes (Y)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'No (N)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'No (N)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'No (N)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'No (N)'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'Colleen'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'Kelley'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:47:16
User entered 'GA'	System	24 Nov 2020 13:46:54

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	24 Nov 2020 13:47:21

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 13:47:21

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 13:47'	System	24 Nov 2020 13:47:21

US3632022

Folder: SAE USA-US120-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:22

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 13:47:21