

US3612010 (Prod: University of Texas- Galveston)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:08:07

All time stamps listed in this document are displayed in GMT

US3612010

Form: Participant Creation

Generated On: 26 Nov 2020 11:08:07

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:08:07

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:08:07

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

Condition	PERIPHERAL ARTERY DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

Condition	CARDIAC CATHERIZATION
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

Condition	PULMONARY NODULES IN RIGHT UPPER LOBE
Start date (dd MMM yyyy)	13 MAY 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

Condition	HEAVY SMOKER
Start date (dd MMM yyyy)	UN UNK 1965
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1965
Start Year (derived)	1965
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

Condition	EMPHYSEMA
Start date (dd MMM yyyy)	08 MAY 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	1 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:50 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 13:50
Height (<i>xxx.x</i>)	73.5 in
Weight (<i>xxx.x</i>)	157 lb
BMI (<i>xxx.x</i>)	20.47552 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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 OVER 65

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 189154

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

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)	1 SEP 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 13:50
Temperature (xxx.x)	99.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	174 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

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)	1 SEP 2020
Time of assessment (00:00-23:59)	15:39 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 15:39
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	47 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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)	1 SEP 2020
What was the treatment time? (00:00-23:59)	15:03 (24 HR)
Treatment Date and Time (derived)	1 SEP 2020 15:03
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	1 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:32 (24 HR)
Collection date and time (derived)	1 SEP 2020 14:32

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:07

Collection date (dd MMM yyyy)			1 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:19	1 SEP 2020 14:19
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐
No ☒

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

PC Time Stamp 01 SEP 2020 15:49

PC Open Date & Time 01 SEP 2020 15:23

PC Close Date & Time 01 SEP 2020 17:53

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	02 SEP 2020 10:45
PC Open Date & Time	01 SEP 2020 18:48
PC Close Date & Time	02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 18:21

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

03 SEP 2020 17:18

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 16:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

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

98.2 °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

05 SEP 2020 14:22

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 14:06

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:21

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

01 SEP 2020 15:49

PC Open Date & Time

01 SEP 2020 15:23

PC Close Date & Time

01 SEP 2020 17:53

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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

02 SEP 2020 10:46

PC Open Date & Time

01 SEP 2020 18:48

PC Close Date & Time

02 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 18:22

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 17:19

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

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

04 SEP 2020 16:54

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 14:23

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

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

06 SEP 2020 14:07

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

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

07 SEP 2020 12:21

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 15:50
PC Open Date & Time	01 SEP 2020 15:23
PC Close Date & Time	01 SEP 2020 17:53

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 10:46
PC Open Date & Time	01 SEP 2020 18:48
PC Close Date & Time	02 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	02 SEP 2020 18:22
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	03 SEP 2020 17:20
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	04 SEP 2020 16:54
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	05 SEP 2020 14:23
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	06 SEP 2020 14:07
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	07 SEP 2020 12:22
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3612010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3612010

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3612010

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3612010

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	11:14 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:14
Temperature (xxx.x)	97.8 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)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 12:32
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3612010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3612010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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)	30 SEP 2020
What was the treatment time? (00:00-23:59)	12:00 (24 HR)
Treatment Date and Time (derived)	30 SEP 2020 12:00
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3612010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	30 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:50 (24 HR)
Collection date and time (derived)	30 SEP 2020 11:50

US3612010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:07

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:54	30 SEP 2020 11:54
Nasopharyngeal Swab 2	No		

US3612010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 12:28

PC Open Date & Time

30 SEP 2020 12:20

PC Close Date & Time

30 SEP 2020 14:50

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 23:03

PC Open Date & Time

30 SEP 2020 15:45

PC Close Date & Time

01 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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 18:17

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 18:04

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 17:50

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp 05 OCT 2020 11:23

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 19:12

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp 06 OCT 2020 20:04

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

30 SEP 2020 12:28

PC Open Date & Time

30 SEP 2020 12:20

PC Close Date & Time

30 SEP 2020 14:50

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 23:04

PC Open Date & Time

30 SEP 2020 15:45

PC Close Date & Time

01 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 18:18

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 18:04

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 17:50

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 11:23

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 19:12

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

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

06 OCT 2020 20:04

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 12:29
PC Open Date & Time	30 SEP 2020 12:20
PC Close Date & Time	30 SEP 2020 14:50

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 23:04
PC Open Date & Time	30 SEP 2020 15:45
PC Close Date & Time	01 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

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

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	02 OCT 2020 18:05
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	03 OCT 2020 17:50
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	05 OCT 2020 11:23
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	05 OCT 2020 19:12
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

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 ☒

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	06 OCT 2020 20:05
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3612010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3612010

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted?

Yes ☒

No ☐

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

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3612010

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3612010

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	28 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:08 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 13:08
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3612010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3612010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	28 OCT 2020
Collection time (<i>00:00-23:59</i>)	13:30 (24 HR)
Collection date and time (derived)	28 OCT 2020 13:30

US3612010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

10 NOV 2020 21:26:48

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 15:12:43
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 12:17:46
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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°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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

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03 JAN 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

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24 JAN 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

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21 FEB 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

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06 JUN 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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09 JUN 2022 00:01

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13 JUN 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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23 JUN 2022 00:01

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27 JUN 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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30 JUN 2022 00:01

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04 JUL 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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11 JUL 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 JUL 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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25 JUL 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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01 AUG 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 AUG 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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15 AUG 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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22 AUG 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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25 AUG 2022 00:01

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29 AUG 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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05 SEP 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3612010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3612010

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

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

US3612010

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3612010

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:08:07

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☐

US3612010

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:08:07

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3612010

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:08:07

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

AEID	USA-US129-2020-MRNA-1273-P30 1000001
Adverse event	ABDOMINAL AORTIC ANEURYSM (3CM)
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)	16 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

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US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

THIS IS AN INITIAL REPORT OF
A 67 YEAR OLD MALE THAT
WAS DIAGNOSED WITH AN
ABDOMINAL AORTIC
ANEURYSM ON 16 OCTOBER
2020. SUBJECT HAS YEARLY CT
SCANS DONE DUE TO HIS
HEAVY SMOKING HISTORY OF
1 1/2 PACKS PER DAY X 60
YEARS. HIS PREVIOUS EXAM
WAS DONE ON 12 SEP 2018 AND
THERE WAS NO FINDING OF AN
ANEURYSM. SUBJECT HAD
THE CT SCAN DONE ON 16
OCTOBER 2020 AND THE
CONDITION WAS FOUND.
SUBJECT IS ASYMPTOMATIC
AND WILL BE FOLLOWED UP
BY AN ADDITIONAL CT SCAN
IN 6 MONTHS PER PRIMARY
CARE PHYSICIAN. SUBJECT
REMAINS ON STUDY FOR
FOLLOW-UP PER PROTOCOL.

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

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

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

v6.020 DTW (1102)

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US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

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

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:08:07

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

Yes ☒

No ☐

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

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

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

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	
Prophylaxis	Yes ☐
	No ☐
Indication	
Dose per administration	
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 ☐

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown _____		
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	☐

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

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

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

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

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3612010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:08:07

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3612010

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:08:07

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

US3612010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:07

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 ☐

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

SAEID	USA-US129-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	301 UNIVERSITY BLVD
Site Address: City	GALVESTON
Site Address: State	TX
Site Address: Postal Code	77555
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:07

SAEID	USA-US129-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	301 UNIVERSITY BLVD
Site Address: City	GALVESTON
Site Address: State	TX
Site Address: Postal Code	77555
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/NOV/2020 11:39
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

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:08:07

SAEID	USA-US129-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	301 UNIVERSITY BLVD
Site Address: City	GALVESTON
Site Address: State	TX
Site Address: Postal Code	77555
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	18/NOV/2020 17:52
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

US3612010 (Prod: University of Texas- Galveston)

US3612010

Form: Participant Creation

Generated On: 26 Nov 2020 11:08:07

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3612010'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Sep 2020 19:45:11

US3612010

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:42:52

US3612010

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 19:45:12

US3612010

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:42:52

US3612010

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	01 Sep 2020 20:42:52

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 19:45:13

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Age](#)

Audit	User	Time (GMT)
User entered '67'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '67'	System	01 Sep 2020 20:43:30

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[White](#)

Audit	User	Time (GMT)
User entered '1'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:06

US3612010

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:30

US3612010

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	01 Sep 2020 20:43:30

US3612010

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '2020'	System	01 Sep 2020 20:43:30

US3612010

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:30

US3612010

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:30

US3612010

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:30

US3612010

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:30

US3612010

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:30

US3612010

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 19:45:12

US3612010

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 20:43:36

US3612010

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:43:36

US3612010

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:08:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 13:58:38

US3612010

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:00:50
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 14:00:50
Data point term sent to Coder	System	02 Sep 2020 13:59:37
User entered 'Hypertension'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 13:59:33

US3612010

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'un UNK 2005'	Kristin Pollock (b) (4)	02 Sep 2020 13:59:33
	(b) (4)	

US3612010

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 13:59:33

US3612010

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 13:59:33

US3612010

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 13:59:33

US3612010

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Kristin Pollock (b) (4)	02 Sep 2020 13:59:33
	(b) (4)	

US3612010

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	02 Sep 2020 13:59:33

US3612010

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '2005'	System	02 Sep 2020 13:59:33

US3612010

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:59:33

US3612010

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:59:33

US3612010

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:25:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:25:51
Data point term sent to Coder	System	18 Nov 2020 21:24:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:01:52
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 14:01:52
Data point term sent to Coder	System	02 Sep 2020 14:00:38
User entered 'High Cholesterol'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 13:59:56

US3612010

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 14:00:20
User entered 'UN UNK 2005' reason for change: Data Entry Error	Kristin Pollock (b) (4)	02 Sep 2020 14:00:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 13:59:56
User entered 'uk UNK 2005' (non-conformant).	Kristin Pollock (b) (4)	02 Sep 2020 13:59:56

US3612010

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Kristin Pollock (b) (4)	02 Sep 2020 13:59:56
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 13:59:56

US3612010

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 13:59:56

US3612010

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Kristin Pollock (b) (4)	02 Sep 2020 13:59:56
	(b) (4)	

US3612010

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	02 Sep 2020 14:00:20
User entered empty.	System	02 Sep 2020 13:59:56

US3612010

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '2005'	System	02 Sep 2020 14:00:20
User entered empty.	System	02 Sep 2020 13:59:56

US3612010

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:59:56

US3612010

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:59:56

US3612010

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:25:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:25:49
Data point term sent to Coder	System	18 Nov 2020 21:24:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:37:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:37:50
Data point term sent to Coder	System	17 Nov 2020 20:37:16
User entered 'CORONARY ARTERY DISEASE'	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:36:50

US3612010

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'UN UNK 2006'	Amy McMahan (b) (4)	17 Nov 2020 20:36:50

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:36:50

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'Yes (Y)'	Amy McMahan (b) (4)	17 Nov 2020 20:36:50

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered empty.	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:36:50

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:36:50

US3612010

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	17 Nov 2020 20:36:50

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '2006'	System	17 Nov 2020 20:36:50

US3612010

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:36:50

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:36:50

US3612010

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User closed query 'PERiPHERAL ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:10:41
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:10:38
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral arterial occlusive disease, LLT: Peripheral arterial disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 23:17:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 23:17:03
Data point term sent to Coder	System	20 Nov 2020 23:16:28
Query 'PERiPHERAL ' answered with 'UPDATED' (Site from CRA).	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 23:16:02
DataPoint Un-verified.	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 23:15:46
Coding entries removed.	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 23:15:46
User entered 'PERIPHERAL ARTERY DISEASE' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 23:15:46
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral arterial occlusive disease, LLT: Peripheral arterial disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:25:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:25:52
User opened query 'PERiPHERAL ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:25:21
Data point term sent to Coder	System	18 Nov 2020 21:24:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral arterial occlusive disease, LLT: Peripheral arterial disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 08:54:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 08:54:01
Data point term sent to Coder	System	17 Nov 2020 20:38:17

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User entered 'PERPHEAL ARTERY DISEASE'	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:37:27

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered empty.	Amy McMahan (b) (4)	17 Nov 2020 20:37:27
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '1'	Amy McMahan (b) (4)	17 Nov 2020 20:37:27

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'Yes (Y)'	Amy McMahan (b) (4)	17 Nov 2020 20:37:27
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered empty.	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:37:27

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:37:27

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:37:27

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:37:27

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:37:27

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:37:27

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac imaging procedures, PT: Catheterisation cardiac, LLT: Cardiac catheterization - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 21:25:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 21:25:48
Data point term sent to Coder	System	18 Nov 2020 21:24:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac imaging procedures, PT: Catheterisation cardiac, LLT: Cardiac catheterization - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:38:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:38:50
Data point term sent to Coder	System	17 Nov 2020 20:38:17
User entered 'CARDIAC CATHERIZATION'	Amy McMahan (b) (4)	17 Nov 2020 20:37:53

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'UN UNK 2007'	Amy McMahan (b) (4)	17 Nov 2020 20:37:53

US3612010

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:37:53

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	17 Nov 2020 20:38:17
User entered 'No (N)' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:38:17
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	17 Nov 2020 20:38:11
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:37:53

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'UN UNK 2007' reason for change:	Amy McMahan (b) (4)	17 Nov 2020 20:38:11
Data Entry Error	(b) (4)	
User entered empty.	Amy McMahan (b) (4)	17 Nov 2020 20:37:53
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:37:53

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	17 Nov 2020 20:37:53

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '2007'	System	17 Nov 2020 20:37:53

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	17 Nov 2020 20:38:11
User entered empty.	System	17 Nov 2020 20:37:53

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '2007'	System	17 Nov 2020 20:38:11
User entered empty.	System	17 Nov 2020 20:37:53

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 21:25:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 21:25:50
Data point term sent to Coder	System	18 Nov 2020 21:24:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 20:56:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 20:56:50
Data point term sent to Coder	System	17 Nov 2020 20:39:18
User entered 'ATRIAL FIBRILLATION'	Amy McMahan (b) (4)	17 Nov 2020 20:38:52

US3612010

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'UN UNK 2018'	Amy McMahan (b) (4)	17 Nov 2020 20:38:52

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:38:52

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'Yes (Y)'	Amy McMahan (b) (4)	17 Nov 2020 20:38:52

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered empty.	Amy McMahan (b) (4)	17 Nov 2020 20:38:52
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:38:52

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	17 Nov 2020 20:38:52

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Nov 2020 20:38:52

US3612010

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:38:52

US3612010

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:38:52

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:25:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:25:50
Data point term sent to Coder	System	18 Nov 2020 21:24:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:36:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:36:01
Data point term sent to Coder	System	17 Nov 2020 20:40:21
User entered 'PULMONARY NODULES IN RIGHT UPPER LOBE'	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:40:13

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '13 May 2016'	Amy McMahan (b) (4)	17 Nov 2020 20:40:13

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:40:13

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'Yes (Y)'	Amy McMahan (b) (4)	17 Nov 2020 20:40:13
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered empty.	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:40:13

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:40:13

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'May 2016'	System	17 Nov 2020 20:40:13

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '2016'	System	17 Nov 2020 20:40:13

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:40:13

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:40:13

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Heavy smoker - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 21:25:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	18 Nov 2020 21:25:48
Data point term sent to Coder	System	18 Nov 2020 21:24:52
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Heavy smoker - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:41:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	17 Nov 2020 20:41:51
Data point term sent to Coder	System	17 Nov 2020 20:41:24
User entered 'HEAVY SMOKER'	Amy McMahan (b) (4)	17 Nov 2020 20:41:11
	(b) (4)	

US3612010

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'UN UNK 1965'	Amy McMahan (b) (4)	17 Nov 2020 20:41:11

US3612010

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:41:11

US3612010

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:41:11

US3612010

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered empty.	Amy McMahan (b) (4)	17 Nov 2020 20:41:11
	(b) (4)	

US3612010

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:41:11

US3612010

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Jan 1965'	System	17 Nov 2020 20:41:11

US3612010

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '1965'	System	17 Nov 2020 20:41:11

US3612010

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:41:11

US3612010

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:41:11

US3612010

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 21:25:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 21:25:49
Data point term sent to Coder	System	18 Nov 2020 21:24:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:57:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:57:50
Data point term sent to Coder	System	17 Nov 2020 20:42:24
User entered 'EMPHYSEMA'	Amy McMahan (b) (4)	17 Nov 2020 20:41:35
	(b) (4)	

US3612010

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '08 May 2018'	Amy McMahan (b) (4)	17 Nov 2020 20:41:35

US3612010

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:41:35

US3612010

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:41:35

US3612010

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered empty.	Amy McMahan (b) (4) (b) (4)	17 Nov 2020 20:41:35

US3612010

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:24:48
User entered '0'	Amy McMahan (b) (4)	17 Nov 2020 20:41:35

US3612010

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'May 2018'	System	17 Nov 2020 20:41:35

US3612010

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Nov 2020 20:41:35

US3612010

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:41:35

US3612010

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:41:35

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '13:50'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 13:50'	System	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '73.5' in	Kristin Pollock (b) (4)	02 Sep 2020 14:04:13
DataPoint set to visible.	(b) (4) System	01 Sep 2020 20:43:36

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '157' lb	Kristin Pollock (b) (4)	02 Sep 2020 14:04:13
DataPoint set to visible.	(b) (4) System	01 Sep 2020 20:43:36

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '20.47552'	System	02 Sep 2020 14:04:13
DataPoint set to visible.	System	01 Sep 2020 20:43:36

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	02 Sep 2020 14:04:13
DataPoint set to visible.	System	01 Sep 2020 20:43:36

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Re-query: Per CDM: Response noted, However kindly consider keeping units and route Blank for data field as Temperature is ND.Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:43:20
Query 'Re-query: Per CDM: Response noted, However kindly consider keeping units and route Blank for data field as Temperature is ND.Thank you.' answered with 'updated' (Site from DM).	Kristin Pollock (b) (4)	09 Sep 2020 15:56:23
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	09 Sep 2020 15:56:12
User opened query 'Re-query: Per CDM: Response noted, However kindly consider keeping units and route Blank for data field as Temperature is ND.Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 05:10:14
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)	09 Sep 2020 05:10:14
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 'updated as requested' (Site from DM).	Kristin Pollock (b) (4)	08 Sep 2020 23:12:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 23:12:20
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)	07 Sep 2020 22:55:07
User entered '99.2' F	Kristin Pollock (b) (4)	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Kristin Pollock (b) (4)	09 Sep 2020 15:56:12
User entered 'Oral (Oral)'	Kristin Pollock (b) (4)	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 23:12:20
User entered '66'	Kristin Pollock (b) (4)	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 23:12:20
User entered '18'	Kristin Pollock (b) (4)	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4) (b) (4)	08 Sep 2020 23:12:20
User entered '174'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 23:12:20
User entered '81'	Kristin Pollock (b) (4)	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 14:04:13

US3612010

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:04:22

US3612010

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	02 Sep 2020 14:04:33
User entered '1 Sep 2020' reason for change: Data Entry Error	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:04:33
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	02 Sep 2020 14:04:22
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:04:22

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

[Specify](#)

Audit	User	Time (GMT)
User entered 'over 65'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '1'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:05:38

US3612010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:41:57

US3612010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:41:57

US3612010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:41:57

US3612010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	01 Sep 2020 20:41:57

US3612010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Sep 2020 19:49:22

US3612010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '189154'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 19:49:22

US3612010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 19:49:22

US3612010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

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)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:42:31

US3612010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:42:31

US3612010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:42:31

US3612010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 20:42:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 20:42:35
User entered 'No (N)' reason for change: Data Entry Error	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:42:35
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 20:42:31
User entered empty.	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:42:31

US3612010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:42:31

US3612010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:51:24
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:01:53

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

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)	09 Sep 2020 05:10:34
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 'updated as requested' (Site from DM).	Kristin Pollock (b) (4)	08 Sep 2020 23:13:31
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	08 Sep 2020 23:13:20
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)	07 Sep 2020 22:55:28
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 23:13:20
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

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)	09 Sep 2020 05:10:34
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 'updated as requested' (Site from DM).	Kristin Pollock (b) (4)	08 Sep 2020 23:13:31
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	08 Sep 2020 23:13:20
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)	07 Sep 2020 22:55:28
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 23:13:20
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '13:50'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 13:50'	System	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99.2' F	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '18'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 05:10:44
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI, not clinically significant.' (Site from System).	Amy McMahan (b) (4)	04 Sep 2020 13:59:17
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Sep 2020 20:46:55
User entered '174'	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

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)	09 Sep 2020 05:10:34
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 'updated as requested' (Site from DM).	Kristin Pollock (b) (4)	08 Sep 2020 23:13:31
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	08 Sep 2020 23:13:20
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)	07 Sep 2020 22:55:28
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Kristin Pollock (b) (4)	08 Sep 2020 23:13:20
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 21:48:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 21:48:05
User entered 'Yes (Y)' reason for change: New Information	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 21:48:05
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 20:46:55
User entered empty.	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020' reason for change: Data Entry Error	Kristin Pollock (b) (4)	01 Sep 2020 21:48:05
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '15:39' reason for change: New Information	Kristin Pollock (b) (4)	01 Sep 2020 21:48:05
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 15:39'	System	01 Sep 2020 21:48:05
User entered empty.	System	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F reason for change: New Information	Kristin Pollock (b) (4)	01 Sep 2020 21:48:05
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: New Information	Kristin Pollock (b) (4)	01 Sep 2020 21:48:05
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '47' reason for change: New Information	Kristin Pollock (b) (4)	01 Sep 2020 21:48:05
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 21:48:05
User entered empty.	System	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '18' reason for change: New Information	Kristin Pollock (b) (4)	01 Sep 2020 21:48:05
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 21:48:05
User entered empty.	System	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 10:18:45
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI, not clinically significant.' (Site from System).	Amy McMahan (b) (4)	04 Sep 2020 13:59:30
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Sep 2020 21:48:05
User entered '170' reason for change: New Information	Kristin Pollock (b) (4)	01 Sep 2020 21:48:05
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 21:48:05
User entered empty.	System	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '84' reason for change: New Information	Kristin Pollock (b) (4)	01 Sep 2020 21:48:05
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 21:48:05
User entered empty.	System	01 Sep 2020 20:46:55

US3612010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:28:10

US3612010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:28:10

US3612010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	01 Sep 2020 20:45:34
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	01 Sep 2020 20:45:34
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	01 Sep 2020 20:45:24
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:45:24

US3612010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:45:24

US3612010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:45:24

US3612010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 20:45:24

US3612010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:45:24

US3612010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '15:03'	Kristin Pollock (b) (4) (b) (4)	01 Sep 2020 20:45:24

US3612010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 15:03'	System	01 Sep 2020 20:45:24

US3612010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Kristin Pollock (b) (4)	01 Sep 2020 20:45:34
User entered empty.	Kristin Pollock (b) (4)	01 Sep 2020 20:45:24

US3612010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Sep 2020 20:45:24

US3612010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 20:45:24

US3612010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:28:49

US3612010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:28:49

US3612010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:32'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:28:49

US3612010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 14:32'	System	02 Sep 2020 14:28:49

US3612010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:29:02

US3612010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kristin Pollock (b) (4)	02 Sep 2020 14:29:02

US3612010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:29:02

US3612010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:19'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:29:02

US3612010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '1 Sep 2020 14:19'	System	02 Sep 2020 14:29:02

US3612010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kristin Pollock (b) (4)	02 Sep 2020 14:29:02

US3612010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 14:29:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 14:29:30
User entered 'No (N)' reason for change: Data Entry Error	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:29:30
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 14:29:02
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:29:02

US3612010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:29:02

US3612010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 14:29:02

US3612010

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:29:42

US3612010

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:29:42

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:48:36', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5280fdd8-6e7f-409e-a46f-2654c829a4f9'	System	01 Sep 2020 20:49:09
User entered 'Yes (Y)'	System	01 Sep 2020 20:49:09

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:48:48', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5280fdd8-6e7f-409e-a46f-2654c829a4f9'	System	01 Sep 2020 20:49:09
User entered '97.8'	System	01 Sep 2020 20:49:09

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:48:55', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5280fdd8-6e7f-409e-a46f-2654c829a4f9'	System	01 Sep 2020 20:49:09
User entered 'No (N)'	System	01 Sep 2020 20:49:09

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:04', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5280fdd8-6e7f-409e-a46f-2654c829a4f9'	System	01 Sep 2020 20:49:09
User entered '01 Sep 2020 15:49'	System	01 Sep 2020 20:49:09

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:23'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 17:53'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:44:50', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'efbb6762-1e53-4a6a-b080-5a934825a754'	System	02 Sep 2020 15:45:22
User entered 'Yes (Y)'	System	02 Sep 2020 15:45:22

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:45:04', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'efbb6762-1e53-4a6a-b080-5a934825a754'	System	02 Sep 2020 15:45:22
User entered '98.6'	System	02 Sep 2020 15:45:22

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:45:10', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'efbb6762-1e53-4a6a-b080-5a934825a754'	System	02 Sep 2020 15:45:22
User entered 'No (N)'	System	02 Sep 2020 15:45:22

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:45:20', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'efbb6762-1e53-4a6a-b080-5a934825a754'	System	02 Sep 2020 15:45:22
User entered '02 Sep 2020 10:45'	System	02 Sep 2020 15:45:22

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 18:48'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 2'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:21:08', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c3464c42-5db3-4551-8f72-457a468db865'	System	02 Sep 2020 23:21:45
User entered 'Yes (Y)'	System	02 Sep 2020 23:21:45

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:21:23', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c3464c42-5db3-4551-8f72-457a468db865'	System	02 Sep 2020 23:21:45
User entered '98.3'	System	02 Sep 2020 23:21:45

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:21:28', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c3464c42-5db3-4551-8f72-457a468db865'	System	02 Sep 2020 23:21:45
User entered 'No (N)'	System	02 Sep 2020 23:21:45

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:21:43', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c3464c42-5db3-4551-8f72-457a468db865'	System	02 Sep 2020 23:21:45
User entered '02 Sep 2020 18:21'	System	02 Sep 2020 23:21:45

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 3'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:18:12', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '88d78494-1eb6-4637-b047-6d47ea86333a'	System	03 Sep 2020 22:18:36
User entered 'Yes (Y)'	System	03 Sep 2020 22:18:36

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:18:21', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '88d78494-1eb6-4637-b047-6d47ea86333a'	System	03 Sep 2020 22:18:36
User entered '98.2'	System	03 Sep 2020 22:18:36

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:18:27', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '88d78494-1eb6-4637-b047-6d47ea86333a'	System	03 Sep 2020 22:18:36
User entered 'No (N)'	System	03 Sep 2020 22:18:36

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:18:35', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '88d78494-1eb6-4637-b047-6d47ea86333a'	System	03 Sep 2020 22:18:36
User entered '03 Sep 2020 17:18'	System	03 Sep 2020 22:18:36

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 4'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:53:08', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'e2f3feeb-ed6f-4584-8a24-ff9d4f47d0d8'	System	04 Sep 2020 21:53:32
User entered 'Yes (Y)'	System	04 Sep 2020 21:53:32

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:53:21', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'e2f3feeb-ed6f-4584-8a24-ff9d4f47d0d8'	System	04 Sep 2020 21:53:32
User entered '98.3'	System	04 Sep 2020 21:53:32

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:53:25', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'e2f3feeb-ed6f-4584-8a24-ff9d4f47d0d8'	System	04 Sep 2020 21:53:32
User entered 'No (N)'	System	04 Sep 2020 21:53:32

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:53:31', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'e2f3feeb-ed6f-4584-8a24-ff9d4f47d0d8'	System	04 Sep 2020 21:53:32
User entered '04 Sep 2020 16:53'	System	04 Sep 2020 21:53:32

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 5'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:22:26', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '3fab9658-7bc2-4722-8203-02f2084e1663'	System	05 Sep 2020 19:22:45
User entered 'Yes (Y)'	System	05 Sep 2020 19:22:45

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:22:36', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '3fab9658-7bc2-4722-8203-02f2084e1663'	System	05 Sep 2020 19:22:45
User entered '98.2'	System	05 Sep 2020 19:22:45

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:22:40', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '3fab9658-7bc2-4722-8203-02f2084e1663'	System	05 Sep 2020 19:22:45
User entered 'No (N)'	System	05 Sep 2020 19:22:45

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:22:43', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '3fab9658-7bc2-4722-8203-02f2084e1663'	System	05 Sep 2020 19:22:45
User entered '05 Sep 2020 14:22'	System	05 Sep 2020 19:22:45

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 6'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:06:32', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2c585d79-2c10-476c-990a-5787d2f19d0e'	System	06 Sep 2020 19:06:54
User entered 'Yes (Y)'	System	06 Sep 2020 19:06:54

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:06:39', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2c585d79-2c10-476c-990a-5787d2f19d0e' User entered '98.1'	System	06 Sep 2020 19:06:54
	System	06 Sep 2020 19:06:54

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:06:44', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2c585d79-2c10-476c-990a-5787d2f19d0e'	System	06 Sep 2020 19:06:54
User entered 'No (N)'	System	06 Sep 2020 19:06:54

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:06:51', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2c585d79-2c10-476c-990a-5787d2f19d0e'	System	06 Sep 2020 19:06:54
User entered '06 Sep 2020 14:06'	System	06 Sep 2020 19:06:54

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 7'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:21:22', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '33e7f0ae-8f97-4fb1-ba8a-8f47176f5a75'	System	07 Sep 2020 17:21:39
User entered 'Yes (Y)'	System	07 Sep 2020 17:21:39

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:21:28', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '33e7f0ae-8f97-4fb1-ba8a-8f47176f5a75'	System	07 Sep 2020 17:21:39
User entered '97.5'	System	07 Sep 2020 17:21:39

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:21:32', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '33e7f0ae-8f97-4fb1-ba8a-8f47176f5a75'	System	07 Sep 2020 17:21:39
User entered 'No (N)'	System	07 Sep 2020 17:21:39

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:21:36', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '33e7f0ae-8f97-4fb1-ba8a-8f47176f5a75'	System	07 Sep 2020 17:21:39
User entered '07 Sep 2020 12:21'	System	07 Sep 2020 17:21:39

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:14', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '3e9c95e0-d6e6-4b3c-9d37-fa1de4e41d18'	System	01 Sep 2020 20:49:36
User entered 'None (1)'	System	01 Sep 2020 20:49:36

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:18', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '3e9c95e0-d6e6-4b3c-9d37-fa1de4e41d18'	System	01 Sep 2020 20:49:36
User entered 'No (N)'	System	01 Sep 2020 20:49:36

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:22', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '3e9c95e0-d6e6-4b3c-9d37-fa1de4e41d18'	System	01 Sep 2020 20:49:36
User entered 'No (N)'	System	01 Sep 2020 20:49:36

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:27', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '3e9c95e0-d6e6-4b3c-9d37-fa1de4e41d18'	System	01 Sep 2020 20:49:36
User entered 'None (1)'	System	01 Sep 2020 20:49:36

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:33', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '3e9c95e0-d6e6-4b3c-9d37-fa1de4e41d18'	System	01 Sep 2020 20:49:36
User entered '01 Sep 2020 15:49'	System	01 Sep 2020 20:49:36

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:23'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 17:53'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:45:28', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '908ace6f-643b-451e-b68b-25773ded1318'	System	02 Sep 2020 15:46:10
User entered 'None (1)'	System	02 Sep 2020 15:46:10

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:45:32', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '908ace6f-643b-451e-b68b-25773ded1318'	System	02 Sep 2020 15:46:10
User entered 'No (N)'	System	02 Sep 2020 15:46:10

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:45:37', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '908ace6f-643b-451e-b68b-25773ded1318'	System	02 Sep 2020 15:46:10
User entered 'No (N)'	System	02 Sep 2020 15:46:10

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:45:51', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '908ace6f-643b-451e-b68b-25773ded1318'	System	02 Sep 2020 15:46:10
User entered 'None (1)'	System	02 Sep 2020 15:46:10

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:46:05', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '908ace6f-643b-451e-b68b-25773ded1318'	System	02 Sep 2020 15:46:10
User entered '02 Sep 2020 10:46'	System	02 Sep 2020 15:46:10

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 18:48'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 2'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:21:48', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0f99c98a-1af8-4309-8106-b99d5f14560d'	System	02 Sep 2020 23:22:11
User entered 'None (1)'	System	02 Sep 2020 23:22:11

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:21:52', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0f99c98a-1af8-4309-8106-b99d5f14560d'	System	02 Sep 2020 23:22:11
User entered 'No (N)'	System	02 Sep 2020 23:22:11

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:21:56', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0f99c98a-1af8-4309-8106-b99d5f14560d'	System	02 Sep 2020 23:22:11
User entered 'No (N)'	System	02 Sep 2020 23:22:11

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:22:00', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0f99c98a-1af8-4309-8106-b99d5f14560d'	System	02 Sep 2020 23:22:11
User entered 'None (1)'	System	02 Sep 2020 23:22:11

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:22:08', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0f99c98a-1af8-4309-8106-b99d5f14560d'	System	02 Sep 2020 23:22:11
User entered '02 Sep 2020 18:22'	System	02 Sep 2020 23:22:11

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 3'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:18:43', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8aa8dfd3-8fa1-46c5-a8fc-219e8cfe5f2c'	System	03 Sep 2020 22:19:08
User entered 'None (1)'	System	03 Sep 2020 22:19:08

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:18:47', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8aa8dfd3-8fa1-46c5-a8fc-219e8cfe5f2c'	System	03 Sep 2020 22:19:08
User entered 'No (N)'	System	03 Sep 2020 22:19:08

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:18:52', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8aa8dfd3-8fa1-46c5-a8fc-219e8cfe5f2c'	System	03 Sep 2020 22:19:08
User entered 'No (N)'	System	03 Sep 2020 22:19:08

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:19:00', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8aa8dfd3-8fa1-46c5-a8fc-219e8cfe5f2c'	System	03 Sep 2020 22:19:08
User entered 'None (1)'	System	03 Sep 2020 22:19:08

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:19:05', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8aa8dfd3-8fa1-46c5-a8fc-219e8cfe5f2c'	System	03 Sep 2020 22:19:08
User entered '03 Sep 2020 17:19'	System	03 Sep 2020 22:19:08

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 4'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:53:47', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '643e57b2-d0c2-4e46-868b-3340dafa6622'	System	04 Sep 2020 21:54:02
User entered 'None (1)'	System	04 Sep 2020 21:54:02

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:53:44', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '643e57b2-d0c2-4e46-868b-3340dafa6622'	System	04 Sep 2020 21:54:02
User entered 'No (N)'	System	04 Sep 2020 21:54:02

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:53:50', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '643e57b2-d0c2-4e46-868b-3340dafa6622'	System	04 Sep 2020 21:54:02
User entered 'No (N)'	System	04 Sep 2020 21:54:02

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:53:54', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '643e57b2-d0c2-4e46-868b-3340dafa6622'	System	04 Sep 2020 21:54:02
User entered 'None (1)'	System	04 Sep 2020 21:54:02

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:54:00', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '643e57b2-d0c2-4e46-868b-3340dafa6622'	System	04 Sep 2020 21:54:02
User entered '04 Sep 2020 16:54'	System	04 Sep 2020 21:54:02

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 5'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:22:49', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '08b35209-366d-4e85-a5f1-4df3ab572c23'	System	05 Sep 2020 19:23:10
User entered 'None (1)'	System	05 Sep 2020 19:23:10

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:22:54', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '08b35209-366d-4e85-a5f1-4df3ab572c23'	System	05 Sep 2020 19:23:10
User entered 'No (N)'	System	05 Sep 2020 19:23:10

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:22:58', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '08b35209-366d-4e85-a5f1-4df3ab572c23'	System	05 Sep 2020 19:23:10
User entered 'No (N)'	System	05 Sep 2020 19:23:10

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:23:02', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '08b35209-366d-4e85-a5f1-4df3ab572c23'	System	05 Sep 2020 19:23:10
User entered 'None (1)'	System	05 Sep 2020 19:23:10

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:23:08', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '08b35209-366d-4e85-a5f1-4df3ab572c23'	System	05 Sep 2020 19:23:10
User entered '05 Sep 2020 14:23'	System	05 Sep 2020 19:23:10

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 6'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:06:59', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '27a5f353-7517-444f-8a48-770ec6e00959'	System	06 Sep 2020 19:07:15
User entered 'None (1)'	System	06 Sep 2020 19:07:15

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:03', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '27a5f353-7517-444f-8a48-770ec6e00959'	System	06 Sep 2020 19:07:15
User entered 'No (N)'	System	06 Sep 2020 19:07:15

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:06', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '27a5f353-7517-444f-8a48-770ec6e00959'	System	06 Sep 2020 19:07:15
User entered 'No (N)'	System	06 Sep 2020 19:07:15

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:10', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '27a5f353-7517-444f-8a48-770ec6e00959'	System	06 Sep 2020 19:07:15
User entered 'None (1)'	System	06 Sep 2020 19:07:15

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:13', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '27a5f353-7517-444f-8a48-770ec6e00959'	System	06 Sep 2020 19:07:15
User entered '06 Sep 2020 14:07'	System	06 Sep 2020 19:07:15

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 7'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:21:41', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'b33b3445-3747-4ac6-9f2e-a3d974b6119f'	System	07 Sep 2020 17:21:56
User entered 'None (1)'	System	07 Sep 2020 17:21:56

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:21:44', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'b33b3445-3747-4ac6-9f2e-a3d974b6119f'	System	07 Sep 2020 17:21:56
User entered 'No (N)'	System	07 Sep 2020 17:21:56

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:21:47', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'b33b3445-3747-4ac6-9f2e-a3d974b6119f'	System	07 Sep 2020 17:21:56
User entered 'No (N)'	System	07 Sep 2020 17:21:56

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:21:51', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'b33b3445-3747-4ac6-9f2e-a3d974b6119f'	System	07 Sep 2020 17:21:56
User entered 'None (1)'	System	07 Sep 2020 17:21:56

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:21:54', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'b33b3445-3747-4ac6-9f2e-a3d974b6119f'	System	07 Sep 2020 17:21:56
User entered '07 Sep 2020 12:21'	System	07 Sep 2020 17:21:56

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:40', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '892d2176-c85a-4641-8f7c-86af04ca4e40'	System	01 Sep 2020 20:50:13
User entered 'None (0)'	System	01 Sep 2020 20:50:13

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:42', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '892d2176-c85a-4641-8f7c-86af04ca4e40'	System	01 Sep 2020 20:50:13
User entered 'None (0)'	System	01 Sep 2020 20:50:13

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:45', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '892d2176-c85a-4641-8f7c-86af04ca4e40'	System	01 Sep 2020 20:50:13
User entered 'None (0)'	System	01 Sep 2020 20:50:13

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:49', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '892d2176-c85a-4641-8f7c-86af04ca4e40'	System	01 Sep 2020 20:50:13
User entered 'None (0)'	System	01 Sep 2020 20:50:13

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:53', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '892d2176-c85a-4641-8f7c-86af04ca4e40'	System	01 Sep 2020 20:50:13
User entered 'None (0)'	System	01 Sep 2020 20:50:13

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:49:56', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '892d2176-c85a-4641-8f7c-86af04ca4e40'	System	01 Sep 2020 20:50:13
User entered 'None (0)'	System	01 Sep 2020 20:50:13

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:50:06', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '892d2176-c85a-4641-8f7c-86af04ca4e40'	System	01 Sep 2020 20:50:13
User entered 'No (N)'	System	01 Sep 2020 20:50:13

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-01T15:50:10', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '892d2176-c85a-4641-8f7c-86af04ca4e40'	System	01 Sep 2020 20:50:13
User entered '01 Sep 2020 15:50'	System	01 Sep 2020 20:50:13

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:23'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 17:53'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:46:12', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'cd35c612-9c0b-4307-aada-afe14554b2d0'	System	02 Sep 2020 15:46:55
User entered 'None (0)'	System	02 Sep 2020 15:46:55

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:46:19', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'cd35c612-9c0b-4307-aada-afe14554b2d0'	System	02 Sep 2020 15:46:55
User entered 'None (0)'	System	02 Sep 2020 15:46:55

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:46:24', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'cd35c612-9c0b-4307-aada-afe14554b2d0'	System	02 Sep 2020 15:46:55
User entered 'None (0)'	System	02 Sep 2020 15:46:55

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:46:27', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'cd35c612-9c0b-4307-aada-afe14554b2d0'	System	02 Sep 2020 15:46:55
User entered 'None (0)'	System	02 Sep 2020 15:46:55

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:46:33', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'cd35c612-9c0b-4307-aada-afe14554b2d0'	System	02 Sep 2020 15:46:55
User entered 'None (0)'	System	02 Sep 2020 15:46:55

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:46:36', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'cd35c612-9c0b-4307-aada-afe14554b2d0'	System	02 Sep 2020 15:46:55
User entered 'None (0)'	System	02 Sep 2020 15:46:55

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:46:46', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'cd35c612-9c0b-4307-aada-afe14554b2d0'	System	02 Sep 2020 15:46:55
User entered 'No (N)'	System	02 Sep 2020 15:46:55

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T10:46:52', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'cd35c612-9c0b-4307-aada-afe14554b2d0'	System	02 Sep 2020 15:46:55
User entered '02 Sep 2020 10:46'	System	02 Sep 2020 15:46:55

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 18:48'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 2'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:22:15', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '4f433d21-ec6e-4820-b15b-c99f50edcd82'	System	02 Sep 2020 23:22:43
User entered 'None (0)'	System	02 Sep 2020 23:22:43

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:22:18', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '4f433d21-ec6e-4820-b15b-c99f50edcd82'	System	02 Sep 2020 23:22:43
User entered 'None (0)'	System	02 Sep 2020 23:22:43

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:22:21', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '4f433d21-ec6e-4820-b15b-c99f50edcd82'	System	02 Sep 2020 23:22:43
User entered 'None (0)'	System	02 Sep 2020 23:22:43

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:22:24', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '4f433d21-ec6e-4820-b15b-c99f50edcd82'	System	02 Sep 2020 23:22:43
User entered 'None (0)'	System	02 Sep 2020 23:22:43

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:22:27', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '4f433d21-ec6e-4820-b15b-c99f50edcd82'	System	02 Sep 2020 23:22:43
User entered 'None (0)'	System	02 Sep 2020 23:22:43

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:22:30', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '4f433d21-ec6e-4820-b15b-c99f50edcd82'	System	02 Sep 2020 23:22:43
User entered 'None (0)'	System	02 Sep 2020 23:22:43

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:22:37', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '4f433d21-ec6e-4820-b15b-c99f50edcd82'	System	02 Sep 2020 23:22:43
User entered 'No (N)'	System	02 Sep 2020 23:22:43

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-02T18:22:41', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '4f433d21-ec6e-4820-b15b-c99f50edcd82'	System	02 Sep 2020 23:22:43
User entered '02 Sep 2020 18:22'	System	02 Sep 2020 23:22:43

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 3'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:19:18', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5c3b4728-171a-4167-8c7f-f6e1dfb7a53d'	System	03 Sep 2020 22:20:08
User entered 'None (0)'	System	03 Sep 2020 22:20:08

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:19:21', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5c3b4728-171a-4167-8c7f-f6e1dfb7a53d'	System	03 Sep 2020 22:20:08
User entered 'None (0)'	System	03 Sep 2020 22:20:08

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:19:34', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5c3b4728-171a-4167-8c7f-f6e1dfb7a53d'	System	03 Sep 2020 22:20:08
User entered 'None (0)'	System	03 Sep 2020 22:20:08

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:19:37', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5c3b4728-171a-4167-8c7f-f6e1dfb7a53d'	System	03 Sep 2020 22:20:08
User entered 'None (0)'	System	03 Sep 2020 22:20:08

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:19:52', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5c3b4728-171a-4167-8c7f-f6e1dfb7a53d'	System	03 Sep 2020 22:20:08
User entered 'None (0)'	System	03 Sep 2020 22:20:08

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:19:56', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5c3b4728-171a-4167-8c7f-f6e1dfb7a53d'	System	03 Sep 2020 22:20:08
User entered 'None (0)'	System	03 Sep 2020 22:20:08

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:20:02', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5c3b4728-171a-4167-8c7f-f6e1dfb7a53d'	System	03 Sep 2020 22:20:08
User entered 'No (N)'	System	03 Sep 2020 22:20:08

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-03T17:20:06', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5c3b4728-171a-4167-8c7f-f6e1dfb7a53d'	System	03 Sep 2020 22:20:08
User entered '03 Sep 2020 17:20'	System	03 Sep 2020 22:20:08

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 4'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:54:14', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1af26087-8a53-4053-961a-35e429ebee1'	System	04 Sep 2020 21:54:47
User entered 'None (0)'	System	04 Sep 2020 21:54:47

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:54:18', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1af26087-8a53-4053-961a-35e429ebee1'	System	04 Sep 2020 21:54:47
User entered 'None (0)'	System	04 Sep 2020 21:54:47

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:54:23', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1af26087-8a53-4053-961a-35e429ebee1'	System	04 Sep 2020 21:54:47
User entered 'None (0)'	System	04 Sep 2020 21:54:47

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:54:26', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1af26087-8a53-4053-961a-35e429ebee1'	System	04 Sep 2020 21:54:47
User entered 'None (0)'	System	04 Sep 2020 21:54:47

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:54:30', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1af26087-8a53-4053-961a-35e429ebee1'	System	04 Sep 2020 21:54:47
User entered 'None (0)'	System	04 Sep 2020 21:54:47

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:54:34', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1af26087-8a53-4053-961a-35e429ebee1'	System	04 Sep 2020 21:54:47
User entered 'None (0)'	System	04 Sep 2020 21:54:47

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:54:41', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1af26087-8a53-4053-961a-35e429ebee1'	System	04 Sep 2020 21:54:47
User entered 'No (N)'	System	04 Sep 2020 21:54:47

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-04T16:54:44', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1af26087-8a53-4053-961a-35e429ebee1'	System	04 Sep 2020 21:54:47
User entered '04 Sep 2020 16:54'	System	04 Sep 2020 21:54:47

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 5'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:23:15', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0c27ee88-135d-465d-95c2-15a021984ed7'	System	05 Sep 2020 19:23:45
User entered 'None (0)'	System	05 Sep 2020 19:23:45

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:23:19', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0c27ee88-135d-465d-95c2-15a021984ed7'	System	05 Sep 2020 19:23:45
User entered 'None (0)'	System	05 Sep 2020 19:23:45

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:23:26', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0c27ee88-135d-465d-95c2-15a021984ed7'	System	05 Sep 2020 19:23:45
User entered 'None (0)'	System	05 Sep 2020 19:23:45

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:23:29', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0c27ee88-135d-465d-95c2-15a021984ed7'	System	05 Sep 2020 19:23:45
User entered 'None (0)'	System	05 Sep 2020 19:23:45

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:23:32', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0c27ee88-135d-465d-95c2-15a021984ed7'	System	05 Sep 2020 19:23:45
User entered 'None (0)'	System	05 Sep 2020 19:23:45

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:23:35', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0c27ee88-135d-465d-95c2-15a021984ed7'	System	05 Sep 2020 19:23:45
User entered 'None (0)'	System	05 Sep 2020 19:23:45

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:23:40', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0c27ee88-135d-465d-95c2-15a021984ed7'	System	05 Sep 2020 19:23:45
User entered 'No (N)'	System	05 Sep 2020 19:23:45

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-05T14:23:43', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0c27ee88-135d-465d-95c2-15a021984ed7'	System	05 Sep 2020 19:23:45
User entered '05 Sep 2020 14:23'	System	05 Sep 2020 19:23:45

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 6'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:19', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '48664f7e-8151-47e9-936c-a09dd4442021'	System	06 Sep 2020 19:07:49
User entered 'None (0)'	System	06 Sep 2020 19:07:49

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:23', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '48664f7e-8151-47e9-936c-a09dd4442021'	System	06 Sep 2020 19:07:49
User entered 'None (0)'	System	06 Sep 2020 19:07:49

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:26', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '48664f7e-8151-47e9-936c-a09dd4442021'	System	06 Sep 2020 19:07:49
User entered 'None (0)'	System	06 Sep 2020 19:07:49

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:29', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '48664f7e-8151-47e9-936c-a09dd4442021'	System	06 Sep 2020 19:07:49
User entered 'None (0)'	System	06 Sep 2020 19:07:49

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:32', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '48664f7e-8151-47e9-936c-a09dd4442021'	System	06 Sep 2020 19:07:49
User entered 'None (0)'	System	06 Sep 2020 19:07:49

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:35', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '48664f7e-8151-47e9-936c-a09dd4442021'	System	06 Sep 2020 19:07:49
User entered 'None (0)'	System	06 Sep 2020 19:07:49

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:41', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '48664f7e-8151-47e9-936c-a09dd4442021'	System	06 Sep 2020 19:07:49
User entered 'No (N)'	System	06 Sep 2020 19:07:49

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-06T14:07:44', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '48664f7e-8151-47e9-936c-a09dd4442021'	System	06 Sep 2020 19:07:49
User entered '06 Sep 2020 14:07'	System	06 Sep 2020 19:07:49

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 7'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:22:00', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5a87ae2b-f8bd-4a66-af57-dbb5c9f14cef'	System	07 Sep 2020 17:22:23
User entered 'None (0)'	System	07 Sep 2020 17:22:23

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:22:03', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5a87ae2b-f8bd-4a66-af57-dbb5c9f14cef' User entered 'None (0)'	System	07 Sep 2020 17:22:23

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:22:06', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5a87ae2b-f8bd-4a66-af57-dbb5c9f14cef' User entered 'None (0)'	System	07 Sep 2020 17:22:23

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:22:08', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5a87ae2b-f8bd-4a66-af57-dbb5c9f14cef'	System	07 Sep 2020 17:22:23
User entered 'None (0)'	System	07 Sep 2020 17:22:23

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:22:11', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5a87ae2b-f8bd-4a66-af57-dbb5c9f14cef'	System	07 Sep 2020 17:22:23
User entered 'None (0)'	System	07 Sep 2020 17:22:23

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:22:14', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5a87ae2b-f8bd-4a66-af57-dbb5c9f14cef' User entered 'None (0)'	System	07 Sep 2020 17:22:23

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:22:18', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5a87ae2b-f8bd-4a66-af57-dbb5c9f14cef' User entered 'No (N)'	System	07 Sep 2020 17:22:23

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-07T12:22:21', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '5a87ae2b-f8bd-4a66-af57-dbb5c9f14cef' User entered '07 Sep 2020 12:22'	System	07 Sep 2020 17:22:23
	System	07 Sep 2020 17:22:23

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:45:24

US3612010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 23:56:32

US3612010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 23:56:32

US3612010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 23:56:32

US3612010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 23:56:32

US3612010

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	09 Sep 2020 23:56:37

US3612010

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 23:56:37

US3612010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	16 Sep 2020 19:40:54

US3612010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	16 Sep 2020 19:40:54

US3612010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kristin Pollock (b) (4) (b) (4)	16 Sep 2020 19:40:54

US3612010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	16 Sep 2020 19:40:54

US3612010

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	16 Sep 2020 19:41:00

US3612010

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:41:00

US3612010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	23 Sep 2020 16:41:32

US3612010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Amy McMahan (b) (4) (b) (4)	23 Sep 2020 16:41:32

US3612010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amy McMahan (b) (4) (b) (4)	23 Sep 2020 16:41:32

US3612010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amy McMahan (b) (4) (b) (4)	23 Sep 2020 16:41:32

US3612010

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	23 Sep 2020 16:41:41

US3612010

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:41:41

US3612010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:08:11

US3612010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '30 Sep 2020' reason for change: Data Entry Error	Kristin Pollock (b) (4)	30 Sep 2020 17:09:13
User entered '29 Sep 2020'	Kristin Pollock (b) (4)	30 Sep 2020 17:08:11

US3612010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:08:11

US3612010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	30 Sep 2020 17:08:11

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '11:14'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:14'	System	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '18'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '153'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 21:14:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 21:14:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 21:14:41
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 17:18:27
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020' reason for change: Data Entry Error	Kristin Pollock (b) (4)	30 Sep 2020 21:14:41
User entered empty.	Kristin Pollock (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '12:32' reason for change: Data Entry Error	Kristin Pollock (b) (4)	30 Sep 2020 21:14:41
User entered empty.	Kristin Pollock (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:32'	System	30 Sep 2020 21:14:41
User entered empty.	System	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F reason for change: Data Entry Error	Kristin Pollock (b) (4)	30 Sep 2020 21:14:41
User entered empty.	Kristin Pollock (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kristin Pollock (b) (4)	30 Sep 2020 21:14:41
User entered empty.	Kristin Pollock (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '85' reason for change: Data Entry Error	Kristin Pollock (b) (4)	30 Sep 2020 21:14:41
User entered empty.	Kristin Pollock (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 21:14:41
User entered empty.	System	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '18' reason for change: Data Entry Error	Kristin Pollock (b) (4)	30 Sep 2020 21:14:41
User entered empty.	Kristin Pollock (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 21:14:41
User entered empty.	System	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '153' reason for change: Data Entry Error	Kristin Pollock (b) (4)	30 Sep 2020 21:14:41
User entered empty.	Kristin Pollock (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 21:14:41
User entered empty.	System	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '75' reason for change: Data Entry Error	Kristin Pollock (b) (4)	30 Sep 2020 21:14:41
User entered empty.	Kristin Pollock (b) (4)	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 21:14:41
User entered empty.	System	30 Sep 2020 17:18:27

US3612010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:19:03

US3612010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:19:03

US3612010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:08:59

US3612010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:08:59

US3612010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:08:59

US3612010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 17:08:59

US3612010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	30 Sep 2020 17:09:13
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	30 Sep 2020 17:09:13
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	30 Sep 2020 17:08:59
User entered '30 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:08:59

US3612010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '12:00'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:08:59

US3612010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:08:59

US3612010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	30 Sep 2020 17:08:59

US3612010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 17:08:59

US3612010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:41

US3612010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:41

US3612010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:50'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:41

US3612010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:50'	System	30 Sep 2020 17:18:41

US3612010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:56

US3612010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:56

US3612010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:56

US3612010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:54'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:56

US3612010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:54'	System	30 Sep 2020 17:18:56

US3612010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:56

US3612010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:56

US3612010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 17:18:56

US3612010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:18:56

US3612010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	30 Sep 2020 21:12:07

US3612010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 21:12:07

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:26:53', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'b5fefb1b-7085-439e-a291-0dd61ac1e4b7'	System	30 Sep 2020 17:28:12
User entered 'Yes (Y)'	System	30 Sep 2020 17:28:12

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:27:55', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'b5fefb1b-7085-439e-a291-0dd61ac1e4b7'	System	30 Sep 2020 17:28:12
User entered '97.8'	System	30 Sep 2020 17:28:12

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:28:03', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'b5fefb1b-7085-439e-a291-0dd61ac1e4b7'	System	30 Sep 2020 17:28:12
User entered 'No (N)'	System	30 Sep 2020 17:28:12

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:28:08', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'b5fefb1b-7085-439e-a291-0dd61ac1e4b7'	System	30 Sep 2020 17:28:12
User entered '30 Sep 2020 12:28'	System	30 Sep 2020 17:28:12

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:20'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 14:50'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:03:13', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '455de5f6-4f77-4270-bfdb-19f61f27bf22'	System	01 Oct 2020 04:03:48
User entered 'Yes (Y)'	System	01 Oct 2020 04:03:48

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:03:24', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '455de5f6-4f77-4270-bfdb-19f61f27bf22'	System	01 Oct 2020 04:03:48
User entered '98.5'	System	01 Oct 2020 04:03:48

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:03:34', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '455de5f6-4f77-4270-bfdb-19f61f27bf22'	System	01 Oct 2020 04:03:48
User entered 'No (N)'	System	01 Oct 2020 04:03:48

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:03:44', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '455de5f6-4f77-4270-bfdb-19f61f27bf22'	System	01 Oct 2020 04:03:48
User entered '30 Sep 2020 23:03'	System	01 Oct 2020 04:03:48

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 15:45'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 2'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:17:32', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'df28deee-be25-4e7c-9700-2ae683918795'	System	01 Oct 2020 23:17:56
User entered 'Yes (Y)'	System	01 Oct 2020 23:17:56

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:17:41', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'df28deee-be25-4e7c-9700-2ae683918795'	System	01 Oct 2020 23:17:56
User entered '98.2'	System	01 Oct 2020 23:17:56

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:17:45', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'df28deee-be25-4e7c-9700-2ae683918795'	System	01 Oct 2020 23:17:56
User entered 'No (N)'	System	01 Oct 2020 23:17:56

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:17:51', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'df28deee-be25-4e7c-9700-2ae683918795' User entered '01 Oct 2020 18:17'	System	01 Oct 2020 23:17:56
	System	01 Oct 2020 23:17:56

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 3'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:08', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '582d64b9-d073-459d-bf4f-177e157c4743'	System	02 Oct 2020 23:04:25
User entered 'Yes (Y)'	System	02 Oct 2020 23:04:25

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:16', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '582d64b9-d073-459d-bf4f-177e157c4743'	System	02 Oct 2020 23:04:25
User entered '98.5'	System	02 Oct 2020 23:04:25

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:20', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '582d64b9-d073-459d-bf4f-177e157c4743'	System	02 Oct 2020 23:04:25
User entered 'No (N)'	System	02 Oct 2020 23:04:25

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:23', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '582d64b9-d073-459d-bf4f-177e157c4743' User entered '02 Oct 2020 18:04'	System	02 Oct 2020 23:04:25
	System	02 Oct 2020 23:04:25

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 4'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:49:48', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'ae4b04ca-11fe-4cf5-bd98-2397a830ebd7'	System	03 Oct 2020 22:50:07
User entered 'Yes (Y)'	System	03 Oct 2020 22:50:07

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:49:56', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'ae4b04ca-11fe-4cf5-bd98-2397a830ebd7'	System	03 Oct 2020 22:50:07
User entered '98.3'	System	03 Oct 2020 22:50:07

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:49:59', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'ae4b04ca-11fe-4cf5-bd98-2397a830ebd7'	System	03 Oct 2020 22:50:07
User entered 'No (N)'	System	03 Oct 2020 22:50:07

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:02', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'ae4b04ca-11fe-4cf5-bd98-2397a830ebd7'	System	03 Oct 2020 22:50:07
User entered '03 Oct 2020 17:50'	System	03 Oct 2020 22:50:07

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 5'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:22:47', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '29819e98-bb90-454f-9d51-f9065ef10a19'	System	05 Oct 2020 16:23:09
User entered 'Yes (Y)'	System	05 Oct 2020 16:23:09

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:22:55', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '29819e98-bb90-454f-9d51-f9065ef10a19'	System	05 Oct 2020 16:23:09
User entered '98.5'	System	05 Oct 2020 16:23:09

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:22:58', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '29819e98-bb90-454f-9d51-f9065ef10a19'	System	05 Oct 2020 16:23:09
User entered 'No (N)'	System	05 Oct 2020 16:23:09

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:02', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '29819e98-bb90-454f-9d51-f9065ef10a19' User entered '05 Oct 2020 11:23'	System	05 Oct 2020 16:23:09
	System	05 Oct 2020 16:23:09

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 6'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:11:46', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '55026854-9331-4a80-9867-404929aa1b5b'	System	06 Oct 2020 00:12:05
User entered 'Yes (Y)'	System	06 Oct 2020 00:12:05

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:11:54', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '55026854-9331-4a80-9867-404929aa1b5b'	System	06 Oct 2020 00:12:05
User entered '98.3'	System	06 Oct 2020 00:12:05

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:11:58', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '55026854-9331-4a80-9867-404929aa1b5b'	System	06 Oct 2020 00:12:05
User entered 'No (N)'	System	06 Oct 2020 00:12:05

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:01', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '55026854-9331-4a80-9867-404929aa1b5b'	System	06 Oct 2020 00:12:05
User entered '05 Oct 2020 19:12'	System	06 Oct 2020 00:12:05

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 7'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:04:18', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'd2c3c432-30b5-444c-af82-4ebbf1fa43f8'	System	07 Oct 2020 01:04:35
User entered 'Yes (Y)'	System	07 Oct 2020 01:04:35

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:04:23', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'd2c3c432-30b5-444c-af82-4ebbf1fa43f8'	System	07 Oct 2020 01:04:35
User entered '98.2'	System	07 Oct 2020 01:04:35

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:04:27', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'd2c3c432-30b5-444c-af82-4ebbf1fa43f8'	System	07 Oct 2020 01:04:35
User entered 'No (N)'	System	07 Oct 2020 01:04:35

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:04:31', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'd2c3c432-30b5-444c-af82-4ebbf1fa43f8' User entered '06 Oct 2020 20:04'	System	07 Oct 2020 01:04:35
	System	07 Oct 2020 01:04:35

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:28:14', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '74370612-3e67-4b72-b6c4-c62588721ba3'	System	30 Sep 2020 17:28:50
User entered 'None (1)'	System	30 Sep 2020 17:28:50

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:28:24', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '74370612-3e67-4b72-b6c4-c62588721ba3'	System	30 Sep 2020 17:28:50
User entered 'No (N)'	System	30 Sep 2020 17:28:50

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:28:29', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '74370612-3e67-4b72-b6c4-c62588721ba3'	System	30 Sep 2020 17:28:50
User entered 'No (N)'	System	30 Sep 2020 17:28:50

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:28:44', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '74370612-3e67-4b72-b6c4-c62588721ba3'	System	30 Sep 2020 17:28:50
User entered 'None (1)'	System	30 Sep 2020 17:28:50

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:28:48', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '74370612-3e67-4b72-b6c4-c62588721ba3'	System	30 Sep 2020 17:28:50
User entered '30 Sep 2020 12:28'	System	30 Sep 2020 17:28:50

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:20'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 14:50'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:03:49', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0f476761-ad2b-4578-b7a0-0d9f1008f414'	System	01 Oct 2020 04:04:09
User entered 'None (1)'	System	01 Oct 2020 04:04:09

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:03:54', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0f476761-ad2b-4578-b7a0-0d9f1008f414'	System	01 Oct 2020 04:04:09
User entered 'No (N)'	System	01 Oct 2020 04:04:09

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:03:59', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0f476761-ad2b-4578-b7a0-0d9f1008f414'	System	01 Oct 2020 04:04:09
User entered 'No (N)'	System	01 Oct 2020 04:04:09

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:04:03', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0f476761-ad2b-4578-b7a0-0d9f1008f414'	System	01 Oct 2020 04:04:09
User entered 'None (1)'	System	01 Oct 2020 04:04:09

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:04:07', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '0f476761-ad2b-4578-b7a0-0d9f1008f414'	System	01 Oct 2020 04:04:09
User entered '30 Sep 2020 23:04'	System	01 Oct 2020 04:04:09

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 15:45'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 2'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:17:58', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '840150b9-4797-480a-9980-b277e2c87eb7'	System	01 Oct 2020 23:18:16
User entered 'None (1)'	System	01 Oct 2020 23:18:16

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:03', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '840150b9-4797-480a-9980-b277e2c87eb7'	System	01 Oct 2020 23:18:16
User entered 'No (N)'	System	01 Oct 2020 23:18:16

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:06', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '840150b9-4797-480a-9980-b277e2c87eb7'	System	01 Oct 2020 23:18:16
User entered 'No (N)'	System	01 Oct 2020 23:18:16

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:10', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '840150b9-4797-480a-9980-b277e2c87eb7'	System	01 Oct 2020 23:18:16
User entered 'None (1)'	System	01 Oct 2020 23:18:16

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:13', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '840150b9-4797-480a-9980-b277e2c87eb7'	System	01 Oct 2020 23:18:16
User entered '01 Oct 2020 18:18'	System	01 Oct 2020 23:18:16

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 3'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:28', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1cf3d627-de8e-46de-9587-b843d2b272f1'	System	02 Oct 2020 23:04:44
User entered 'None (1)'	System	02 Oct 2020 23:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:33', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1cf3d627-de8e-46de-9587-b843d2b272f1'	System	02 Oct 2020 23:04:44
User entered 'No (N)'	System	02 Oct 2020 23:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:36', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1cf3d627-de8e-46de-9587-b843d2b272f1'	System	02 Oct 2020 23:04:44
User entered 'No (N)'	System	02 Oct 2020 23:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:39', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1cf3d627-de8e-46de-9587-b843d2b272f1'	System	02 Oct 2020 23:04:44
User entered 'None (1)'	System	02 Oct 2020 23:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:42', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '1cf3d627-de8e-46de-9587-b843d2b272f1' User entered '02 Oct 2020 18:04'	System	02 Oct 2020 23:04:44
	System	02 Oct 2020 23:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 4'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:07', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '36de3151-4336-438b-876b-0000866fcf8a'	System	03 Oct 2020 22:50:22
User entered 'None (1)'	System	03 Oct 2020 22:50:22

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:10', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '36de3151-4336-438b-876b-0000866fcf8a'	System	03 Oct 2020 22:50:22
User entered 'No (N)'	System	03 Oct 2020 22:50:22

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:14', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '36de3151-4336-438b-876b-0000866fcf8a'	System	03 Oct 2020 22:50:22
User entered 'No (N)'	System	03 Oct 2020 22:50:22

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:17', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '36de3151-4336-438b-876b-0000866fcf8a' User entered 'None (1)'	System	03 Oct 2020 22:50:22
	System	03 Oct 2020 22:50:22

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:20', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '36de3151-4336-438b-876b-0000866fcf8a' User entered '03 Oct 2020 17:50'	System	03 Oct 2020 22:50:22
	System	03 Oct 2020 22:50:22

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 5'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:07', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f32bf4b8-faf2-409f-bfda-c311b4427b85'	System	05 Oct 2020 16:23:26
User entered 'None (1)'	System	05 Oct 2020 16:23:26

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:10', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f32bf4b8-faf2-409f-bfda-c311b4427b85'	System	05 Oct 2020 16:23:26
User entered 'No (N)'	System	05 Oct 2020 16:23:26

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:14', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f32bf4b8-faf2-409f-bfda-c311b4427b85'	System	05 Oct 2020 16:23:26
User entered 'No (N)'	System	05 Oct 2020 16:23:26

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:16', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f32bf4b8-faf2-409f-bfda-c311b4427b85'	System	05 Oct 2020 16:23:26
User entered 'None (1)'	System	05 Oct 2020 16:23:26

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:19', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f32bf4b8-faf2-409f-bfda-c311b4427b85'	System	05 Oct 2020 16:23:26
User entered '05 Oct 2020 11:23'	System	05 Oct 2020 16:23:26

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 6'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:05', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2ffcaeb7-327d-40bf-816c-93a5e687ca6a'	System	06 Oct 2020 00:12:21
User entered 'None (1)'	System	06 Oct 2020 00:12:21

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:09', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2ffcaeb7-327d-40bf-816c-93a5e687ca6a'	System	06 Oct 2020 00:12:21
User entered 'No (N)'	System	06 Oct 2020 00:12:21

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:13', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2ffcaeb7-327d-40bf-816c-93a5e687ca6a'	System	06 Oct 2020 00:12:21
User entered 'No (N)'	System	06 Oct 2020 00:12:21

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:15', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2ffcaeb7-327d-40bf-816c-93a5e687ca6a'	System	06 Oct 2020 00:12:21
User entered 'None (1)'	System	06 Oct 2020 00:12:21

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:18', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2ffcaeb7-327d-40bf-816c-93a5e687ca6a'	System	06 Oct 2020 00:12:21
User entered '05 Oct 2020 19:12'	System	06 Oct 2020 00:12:21

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 7'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:04:36', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f49b2bd8-fdff-4048-bb56-591a0f044cd1'	System	07 Oct 2020 01:04:52
User entered 'None (1)'	System	07 Oct 2020 01:04:52

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:04:39', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f49b2bd8-fdff-4048-bb56-591a0f044cd1'	System	07 Oct 2020 01:04:52
User entered 'No (N)'	System	07 Oct 2020 01:04:52

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:04:41', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f49b2bd8-fdff-4048-bb56-591a0f044cd1'	System	07 Oct 2020 01:04:52
User entered 'No (N)'	System	07 Oct 2020 01:04:52

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:04:44', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f49b2bd8-fdff-4048-bb56-591a0f044cd1'	System	07 Oct 2020 01:04:52
User entered 'None (1)'	System	07 Oct 2020 01:04:52

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:04:47', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f49b2bd8-fdff-4048-bb56-591a0f044cd1' User entered '06 Oct 2020 20:04'	System	07 Oct 2020 01:04:52
	System	07 Oct 2020 01:04:52

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:28:53', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '41b5626e-209e-4128-b04f-18b71530732b'	System	30 Sep 2020 17:29:14
User entered 'None (0)'	System	30 Sep 2020 17:29:14

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:28:55', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '41b5626e-209e-4128-b04f-18b71530732b' User entered 'None (0)'	System	30 Sep 2020 17:29:14
	System	30 Sep 2020 17:29:14

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:28:57', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '41b5626e-209e-4128-b04f-18b71530732b'	System	30 Sep 2020 17:29:14
User entered 'None (0)'	System	30 Sep 2020 17:29:14

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:28:59', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '41b5626e-209e-4128-b04f-18b71530732b' User entered 'None (0)'	System	30 Sep 2020 17:29:14
	System	30 Sep 2020 17:29:14

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:29:01', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '41b5626e-209e-4128-b04f-18b71530732b'	System	30 Sep 2020 17:29:14
User entered 'None (0)'	System	30 Sep 2020 17:29:14

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:29:03', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '41b5626e-209e-4128-b04f-18b71530732b'	System	30 Sep 2020 17:29:14
User entered 'None (0)'	System	30 Sep 2020 17:29:14

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:29:08', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '41b5626e-209e-4128-b04f-18b71530732b'	System	30 Sep 2020 17:29:14
User entered 'No (N)'	System	30 Sep 2020 17:29:14

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T12:29:11', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '41b5626e-209e-4128-b04f-18b71530732b' User entered '30 Sep 2020 12:29'	System	30 Sep 2020 17:29:14
	System	30 Sep 2020 17:29:14

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:20'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 14:50'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:04:16', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8f69362d-6362-4111-b7b4-e72bc7931dd2'	System	01 Oct 2020 04:04:44
User entered 'None (0)'	System	01 Oct 2020 04:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:04:19', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8f69362d-6362-4111-b7b4-e72bc7931dd2'	System	01 Oct 2020 04:04:44
User entered 'None (0)'	System	01 Oct 2020 04:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:04:22', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8f69362d-6362-4111-b7b4-e72bc7931dd2'	System	01 Oct 2020 04:04:44
User entered 'None (0)'	System	01 Oct 2020 04:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:04:25', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8f69362d-6362-4111-b7b4-e72bc7931dd2'	System	01 Oct 2020 04:04:44
User entered 'None (0)'	System	01 Oct 2020 04:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:04:28', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8f69362d-6362-4111-b7b4-e72bc7931dd2'	System	01 Oct 2020 04:04:44
User entered 'None (0)'	System	01 Oct 2020 04:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:04:30', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8f69362d-6362-4111-b7b4-e72bc7931dd2'	System	01 Oct 2020 04:04:44
User entered 'None (0)'	System	01 Oct 2020 04:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:04:37', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8f69362d-6362-4111-b7b4-e72bc7931dd2'	System	01 Oct 2020 04:04:44
User entered 'No (N)'	System	01 Oct 2020 04:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-09-30T23:04:40', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8f69362d-6362-4111-b7b4-e72bc7931dd2'	System	01 Oct 2020 04:04:44
User entered '30 Sep 2020 23:04'	System	01 Oct 2020 04:04:44

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 15:45'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 2'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:18', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '7fb8dc84-3f89-4acf-b3c9-fe0b38cc941e'	System	01 Oct 2020 23:18:43
User entered 'None (0)'	System	01 Oct 2020 23:18:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:20', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '7fb8dc84-3f89-4acf-b3c9-fe0b38cc941e' User entered 'None (0)'	System	01 Oct 2020 23:18:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:24', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '7fb8dc84-3f89-4acf-b3c9-fe0b38cc941e'	System	01 Oct 2020 23:18:43
User entered 'None (0)'	System	01 Oct 2020 23:18:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:26', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '7fb8dc84-3f89-4acf-b3c9-fe0b38cc941e'	System	01 Oct 2020 23:18:43
User entered 'None (0)'	System	01 Oct 2020 23:18:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:29', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '7fb8dc84-3f89-4acf-b3c9-fe0b38cc941e'	System	01 Oct 2020 23:18:43
User entered 'None (0)'	System	01 Oct 2020 23:18:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:31', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '7fb8dc84-3f89-4acf-b3c9-fe0b38cc941e'	System	01 Oct 2020 23:18:43
User entered 'None (0)'	System	01 Oct 2020 23:18:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:35', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '7fb8dc84-3f89-4acf-b3c9-fe0b38cc941e'	System	01 Oct 2020 23:18:43
User entered 'No (N)'	System	01 Oct 2020 23:18:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-01T18:18:39', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '7fb8dc84-3f89-4acf-b3c9-fe0b38cc941e'	System	01 Oct 2020 23:18:43
User entered '01 Oct 2020 18:18'	System	01 Oct 2020 23:18:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 3'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:47', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '95d48ea6-cac1-48e6-906e-677211ed9803'	System	02 Oct 2020 23:05:09
User entered 'None (0)'	System	02 Oct 2020 23:05:09

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:49', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '95d48ea6-cac1-48e6-906e-677211ed9803'	System	02 Oct 2020 23:05:09
User entered 'None (0)'	System	02 Oct 2020 23:05:09

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:51', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '95d48ea6-cac1-48e6-906e-677211ed9803'	System	02 Oct 2020 23:05:09
User entered 'None (0)'	System	02 Oct 2020 23:05:09

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:53', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '95d48ea6-cac1-48e6-906e-677211ed9803' User entered 'None (0)'	System	02 Oct 2020 23:05:09
	System	02 Oct 2020 23:05:09

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:55', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '95d48ea6-cac1-48e6-906e-677211ed9803'	System	02 Oct 2020 23:05:09
User entered 'None (0)'	System	02 Oct 2020 23:05:09

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:04:58', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '95d48ea6-cac1-48e6-906e-677211ed9803'	System	02 Oct 2020 23:05:09
User entered 'None (0)'	System	02 Oct 2020 23:05:09

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:05:02', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '95d48ea6-cac1-48e6-906e-677211ed9803'	System	02 Oct 2020 23:05:09
User entered 'No (N)'	System	02 Oct 2020 23:05:09

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-02T18:05:05', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '95d48ea6-cac1-48e6-906e-677211ed9803' User entered '02 Oct 2020 18:05'	System	02 Oct 2020 23:05:09
	System	02 Oct 2020 23:05:09

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 4'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:24', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8a5798b1-e216-4979-9d4b-a9829d8cccb7'	System	03 Oct 2020 22:50:45
User entered 'None (0)'	System	03 Oct 2020 22:50:45

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:26', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8a5798b1-e216-4979-9d4b-a9829d8cccb7'	System	03 Oct 2020 22:50:45
User entered 'None (0)'	System	03 Oct 2020 22:50:45

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:29', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8a5798b1-e216-4979-9d4b-a9829d8cccb7'	System	03 Oct 2020 22:50:45
User entered 'None (0)'	System	03 Oct 2020 22:50:45

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:31', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8a5798b1-e216-4979-9d4b-a9829d8cccb7'	System	03 Oct 2020 22:50:45
User entered 'None (0)'	System	03 Oct 2020 22:50:45

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:34', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8a5798b1-e216-4979-9d4b-a9829d8cccb7'	System	03 Oct 2020 22:50:45
User entered 'None (0)'	System	03 Oct 2020 22:50:45

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:36', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8a5798b1-e216-4979-9d4b-a9829d8cccb7'	System	03 Oct 2020 22:50:45
User entered 'None (0)'	System	03 Oct 2020 22:50:45

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:39', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8a5798b1-e216-4979-9d4b-a9829d8cccb7'	System	03 Oct 2020 22:50:45
User entered 'No (N)'	System	03 Oct 2020 22:50:45

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-03T17:50:42', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '8a5798b1-e216-4979-9d4b-a9829d8cccb7' User entered '03 Oct 2020 17:50'	System	03 Oct 2020 22:50:45
	System	03 Oct 2020 22:50:45

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 5'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:25', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f6bc0eef-fb0b-43ef-ac82-07606bab926f' User entered 'None (0)'	System	05 Oct 2020 16:23:49

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:28', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f6bc0eef-fb0b-43ef-ac82-07606bab926f' User entered 'None (0)'	System	05 Oct 2020 16:23:49

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:30', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f6bc0eef-fb0b-43ef-ac82-07606bab926f' User entered 'None (0)'	System	05 Oct 2020 16:23:49

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:32', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f6bc0eef-fb0b-43ef-ac82-07606bab926f' User entered 'None (0)'	System	05 Oct 2020 16:23:49

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:35', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f6bc0eef-fb0b-43ef-ac82-07606bab926f' User entered 'None (0)'	System	05 Oct 2020 16:23:49

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:39', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f6bc0eef-fb0b-43ef-ac82-07606bab926f' User entered 'None (0)'	System	05 Oct 2020 16:23:49
	System	05 Oct 2020 16:23:49

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:44', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f6bc0eef-fb0b-43ef-ac82-07606bab926f' User entered 'No (N)'	System	05 Oct 2020 16:23:49

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T11:23:47', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'f6bc0eef-fb0b-43ef-ac82-07606bab926f' User entered '05 Oct 2020 11:23'	System	05 Oct 2020 16:23:49
	System	05 Oct 2020 16:23:49

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 6'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:22', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c376b08a-0ee8-46ff-a78b-95fa13f42ae2'	System	06 Oct 2020 00:12:43
User entered 'None (0)'	System	06 Oct 2020 00:12:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:25', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c376b08a-0ee8-46ff-a78b-95fa13f42ae2'	System	06 Oct 2020 00:12:43
User entered 'None (0)'	System	06 Oct 2020 00:12:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:27', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c376b08a-0ee8-46ff-a78b-95fa13f42ae2'	System	06 Oct 2020 00:12:43
User entered 'None (0)'	System	06 Oct 2020 00:12:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:29', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c376b08a-0ee8-46ff-a78b-95fa13f42ae2'	System	06 Oct 2020 00:12:43
User entered 'None (0)'	System	06 Oct 2020 00:12:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:31', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c376b08a-0ee8-46ff-a78b-95fa13f42ae2'	System	06 Oct 2020 00:12:43
User entered 'None (0)'	System	06 Oct 2020 00:12:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:33', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c376b08a-0ee8-46ff-a78b-95fa13f42ae2'	System	06 Oct 2020 00:12:43
User entered 'None (0)'	System	06 Oct 2020 00:12:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:35', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c376b08a-0ee8-46ff-a78b-95fa13f42ae2'	System	06 Oct 2020 00:12:43
User entered 'No (N)'	System	06 Oct 2020 00:12:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-05T19:12:38', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'c376b08a-0ee8-46ff-a78b-95fa13f42ae2'	System	06 Oct 2020 00:12:43
User entered '05 Oct 2020 19:12'	System	06 Oct 2020 00:12:43

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:08:59
User entered 'Day 7'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:04:52', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'fc7b5e36-c52b-4c8c-b74c-d3a819a4c3ae'	System	07 Oct 2020 01:05:16
User entered 'None (0)'	System	07 Oct 2020 01:05:16

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:04:58', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'fc7b5e36-c52b-4c8c-b74c-d3a819a4c3ae'	System	07 Oct 2020 01:05:16
User entered 'None (0)'	System	07 Oct 2020 01:05:16

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:05:00', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'fc7b5e36-c52b-4c8c-b74c-d3a819a4c3ae'	System	07 Oct 2020 01:05:16
User entered 'None (0)'	System	07 Oct 2020 01:05:16

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:05:03', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'fc7b5e36-c52b-4c8c-b74c-d3a819a4c3ae'	System	07 Oct 2020 01:05:16
User entered 'None (0)'	System	07 Oct 2020 01:05:16

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:05:05', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'fc7b5e36-c52b-4c8c-b74c-d3a819a4c3ae'	System	07 Oct 2020 01:05:16
User entered 'None (0)'	System	07 Oct 2020 01:05:16

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:05:08', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'fc7b5e36-c52b-4c8c-b74c-d3a819a4c3ae'	System	07 Oct 2020 01:05:16
User entered 'None (0)'	System	07 Oct 2020 01:05:16

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:05:11', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'fc7b5e36-c52b-4c8c-b74c-d3a819a4c3ae'	System	07 Oct 2020 01:05:16
User entered 'No (N)'	System	07 Oct 2020 01:05:16

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-10-06T20:05:14', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'fc7b5e36-c52b-4c8c-b74c-d3a819a4c3ae'	System	07 Oct 2020 01:05:16
User entered '06 Oct 2020 20:05'	System	07 Oct 2020 01:05:16

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 17:08:59

US3612010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 17:08:59

US3612010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 20:43:00

US3612010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '07 Oct 2020'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 20:43:00

US3612010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 20:43:00

US3612010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 20:43:00

US3612010

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 20:43:04

US3612010

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 20:43:04

US3612010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	14 Oct 2020 19:48:21

US3612010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Amber Stanford (b) (4) (b) (4)	14 Oct 2020 19:48:21

US3612010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	14 Oct 2020 19:48:21

US3612010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amber Stanford (b) (4) (b) (4)	14 Oct 2020 19:48:21

US3612010

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	14 Oct 2020 19:48:27

US3612010

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:48:27

US3612010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	21 Oct 2020 20:29:45

US3612010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Kristin Pollock (b) (4) (b) (4)	21 Oct 2020 20:29:45

US3612010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kristin Pollock (b) (4) (b) (4)	21 Oct 2020 20:29:45

US3612010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	21 Oct 2020 20:29:45

US3612010

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	21 Oct 2020 20:29:50

US3612010

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:29:50

US3612010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:26:38

US3612010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:26:38

US3612010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:26:38

US3612010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	28 Oct 2020 19:26:38

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '13:08'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '28 Oct 2020 13:08'	System	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '18'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '162'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Oct 2020 19:27:39

US3612010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:50

US3612010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:27:50

US3612010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:28:06

US3612010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:28:06

US3612010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:30'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:28:06

US3612010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '28 Oct 2020 13:30'	System	28 Oct 2020 19:28:06

US3612010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	28 Oct 2020 19:28:12

US3612010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 19:28:12

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 71'	System	01 Sep 2020 20:45:24

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-11-10T21:26:38', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'e4a0e13f-68f2-4508-a10b-2e852304e8fd'	System	11 Nov 2020 03:26:51
User entered 'No (N)'	System	11 Nov 2020 03:26:51

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Have you been exposed to someone with 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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-11-10T21:26:44', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'e4a0e13f-68f2-4508-a10b-2e852304e8fd' User entered 'No (N)'	System	11 Nov 2020 03:26:51

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-11-10T21:26:48', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: 'e4a0e13f-68f2-4508-a10b-2e852304e8fd' User entered '10 Nov 2020 21:26:48'	System	11 Nov 2020 03:26:51
	System	11 Nov 2020 03:26:51

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 20:45:24

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered 'Day 78'	System	01 Sep 2020 20:45:24

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-11-16T15:12:33', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2bd8f787-061d-4408-b1ea-277cba939094'	System	16 Nov 2020 21:12:48
User entered 'No (N)'	System	16 Nov 2020 21:12:48

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Have you been exposed to someone with 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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-11-16T15:12:37', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2bd8f787-061d-4408-b1ea-277cba939094'	System	16 Nov 2020 21:12:48
User entered 'No (N)'	System	16 Nov 2020 21:12:48

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-11-16T15:12:43', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '2bd8f787-061d-4408-b1ea-277cba939094' User entered '16 Nov 2020 15:12:43'	System	16 Nov 2020 21:12:48
	System	16 Nov 2020 21:12:48

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 20:45:24

US3612010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 20:45:24
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 20:45:24

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-11-23T12:17:26', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '03910adf-d0a9-490f-a8ef-24c0c07e8440'	System	23 Nov 2020 18:17:49
User entered 'No (N)'	System	23 Nov 2020 18:17:49

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Have you been exposed to someone with 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 (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-11-23T12:17:37', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '03910adf-d0a9-490f-a8ef-24c0c07e8440'	System	23 Nov 2020 18:17:49
User entered 'No (N)'	System	23 Nov 2020 18:17:49

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DB597B0-7DD6-4973-B08B-CA3540F163BF)', Time: '2020-11-23T12:17:46', User OID: 'PatientReportedOutcome (US3612010)', ODM File OID: '03910adf-d0a9-490f-a8ef-24c0c07e8440'	System	23 Nov 2020 18:17:49
User entered '23 Nov 2020 12:17:46'	System	23 Nov 2020 18:17:49

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 22:01:20

US3612010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:01:20
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 22:01:20

US3612010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	24 Nov 2020 20:20:42

US3612010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered '24 Nov 2020'	Amber Stanford (b) (4) (b) (4)	24 Nov 2020 20:20:42

US3612010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	24 Nov 2020 20:20:42

US3612010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amber Stanford (b) (4) (b) (4)	24 Nov 2020 20:20:42

US3612010

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	24 Nov 2020 20:20:51

US3612010

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:20:51

US3612010

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:08:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:36:13
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:53:23

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:33:14
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:38:54
User entered 'USA-US129-2020-mRNA-1273-P301000001'	System	09 Nov 2020 16:38:47
User entered 'New'	(b) (4), (b) (6)	09 Nov 2020 16:38:47

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:33:17
User coded data point as SOC: Vascular disorders, HLGT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic aneurysm, LLT: Abdominal aortic aneurysm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:22:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:22:26
Data point term sent to Coder	System	06 Nov 2020 16:55:35
User entered 'Abdominal Aortic Aneurysm (3cm)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:33:19
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:33:21
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:33:24
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:33:40
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to develop adverse event or was diagnosed. Please consider updating event start date to the onset date that abdominal aortic aneurysm was discovered (16-Oct-2020), since asymptomatic. If not updating the start date, please clarify.' (Site from Safety). Query 'PV Query: Per protocol, SAE start date should be when the subject began to develop adverse event or was diagnosed. Please consider updating event start date to the onset date that abdominal aortic aneurysm was discovered (16-Oct-2020), since asymptomatic. If not updating the start date, please clarify.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 17:41:13
User entered '16 Oct 2020' reason for change: Data Entry Error	Amy McMahan (b) (4)	17 Nov 2020 16:37:57
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to develop adverse event or was diagnosed. Please consider updating event start date to the onset date that abdominal aortic aneurysm was discovered (16-Oct-2020), since asymptomatic. If not updating the start date, please clarify.' (Site from Safety). User entered '21 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 16:12:30
	(b) (4)	16 Nov 2020 15:56:30
	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:33:46
User entered empty.	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:33:48
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:33:51
User closed query 'PV Query: Please provide the event end date when available.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 17:41:20
Query 'PV Query: Please provide the event end date when available.' answered with 'There will be no end date' (Site from Safety).	Amy McMahan (b) (4)	17 Nov 2020 16:12:15
User opened query 'PV Query: Please provide the event end date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 15:57:25
User entered empty.	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:33:55
User entered empty.	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:33:57
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Per AE log in source, NO was selected for AE serious? please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:07:21
Query 'Per AE log in source, NO was selected for AE serious? please reconcile. ' answered with 'updated' (Site from CRA).	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 23:14:04
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User opened query 'Per AE log in source, NO was selected for AE serious? please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:34:59
User entered 'Yes (Y)' reason for change: New Information	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 19:50:11
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:01
User entered '0'	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '1' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Nov 2020 19:50:11
User entered '0'	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'Not Related (NOT RELATED)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'Not Related (NOT RELATED)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'Not Applicable (NOT APPLICABLE)'	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '1'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 17:41:33
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Not expected to resolve.' (Site from Safety).	Amy McMahan (b) (4)	17 Nov 2020 16:16:25
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 15:57:05
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 16:54:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 16:54:49
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Nov 2020 16:54:49
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 16:54:35
User entered empty.	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 17:41:43
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 17:41:40
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'N/A' (Site from Safety).	Amy McMahan (b) (4)	17 Nov 2020 16:37:11
Query 'PV Query: Please provide the results of any COVID-19 testing performed, including date of collection and type of testing. If not done, please state so.' answered with 'N/A' (Site from Safety).	Amy McMahan (b) (4)	17 Nov 2020 16:34:47
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 15:57:42
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 15:56:52

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THIS IS AN INITIAL REPORT OF A 67 YEAR OLD MALE THAT WAS DIAGNOSED WITH AN ABDOMINAL AORTIC ANEURYSM ON 16 OCTOBER 2020. SUBJECT HAS YEARLY CT SCANS DONE DUE TO HIS HEAVY SMOKING HISTORY OF 1 1/2 PACKS PER DAY X 60 YEARS. HIS PREVIOUS EXAM WAS DONE ON 12 SEP 2018 AND THERE WAS NO FINDING OF AN ANEURYSM. SUBJECT HAD THE CT SCAN DONE ON 16 OCTOBER 2020 AND THE CONDITION WAS FOUND. SUBJECT IS ASYMPTOMATIC AND WILL BE FOLLOWED UP BY AN ADDITIONAL CT SCAN IN 6 MONTHS PER PRIMARY CARE PHYSICIAN. SUBJECT REMAINS ON STUDY FOR FOLLOW-UP PER PROTOCOL.' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Nov 2020 20:10:29
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	06 Nov 2020 20:10:01
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	06 Nov 2020 20:10:01
User entered 'This is an initial report of a 67 year old male that was diagnosed with an Abdominal Aortic Aneurysm on 16 October 2020. Subject has yearly CT scans done due to his heavy smoking history of 1 1/2 packs per day x 60 years. His previous exam was done on 12 Sep 2018 and there was no finding of an aneurysm. Subject had the CT scan done on 16 October 2020 and the condition was found. Subject is asymptomatic and will be followed up by an addition CT scan in 6 months per primary care physician. Subject remains on study for follow-up per protocol.' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Nov 2020 20:10:01
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	06 Nov 2020 19:50:11
User entered empty.	Kristin Pollock (b) (4)	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 19:50:11
User entered '0'	System	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 16:54:35

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 16:57:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 16:57:29
Data point term sent to Coder	System	06 Nov 2020 16:56:37
User entered 'Hyponatremia'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '21 Oct 2020'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'Not Related (NOT RELATED)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'Not Related (NOT RELATED)'	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered 'Not Applicable (NOT APPLICABLE)'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '1'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered '0'	Kristin Pollock (b) (4)	06 Nov 2020 16:55:44
	(b) (4)	

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 16:55:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 16:55:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:53
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 16:55:44
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:35:16
User entered empty.	Kristin Pollock (b) (4) (b) (4)	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 16:55:44

US3612010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 16:55:44

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:08:07

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:36:30
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:37:33

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per AE log patient takes Lipitor 20mg PO daily for high cholesterol, not prophylactically, its not a vaccine, started Unk2005, ongoing, and not taken for a solicited event. Per AE log patient also takes metoprolol ER 25mg PO daily for hypertension, not prophylactically, its not a vaccine, started Unk2005, ongoing, and not taken for a solicited event.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:07:43
Query 'Per AE log patient takes Lipitor 20mg PO daily for high cholesterol, not prophylactically, its not a vaccine, started Unk2005, ongoing, and not taken for a solicited event. Per AE log patient also takes metoprolol ER 25mg PO daily for hypertension, not prophylactically, its not a vaccine, started Unk2005, ongoing, and not taken for a solicited event.' answered with 'updated.' (Site from CRA).	Amy McMahan (b) (4)	20 Nov 2020 22:17:58
User opened query 'Per AE log patient takes Lipitor 20mg PO daily for high cholesterol, not prophylactically, its not a vaccine, started Unk2005, ongoing, and not taken for a solicited event. Per AE log patient also takes metoprolol ER 25mg PO daily for hypertension, not prophylactically, its not a vaccine, started Unk2005, ongoing, and not taken for a solicited event.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:39:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 14:42:44
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 14:42:44
Data point term sent to Coder	System	02 Sep 2020 14:41:15
User entered 'Lisinopril'	Kristin Pollock (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 13:58:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 13:58:30
User entered 'No (N)' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	04 Sep 2020 13:58:30
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 14:40:30
User entered empty.	Kristin Pollock (b) (4) (b) (4)	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 14:40:30

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 22:21:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 22:21:03
Data point term sent to Coder	System	20 Nov 2020 22:19:50
User entered 'Lipitor'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:13
User entered 'No (N)'	Amy McMahan (b) (4)	20 Nov 2020 22:19:41
	(b) (4)	

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:16
User entered 'High Cholesterol'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:18
User entered '20'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:20
User entered 'mg (mg)'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:22
User entered empty.	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:25
User entered 'once daily (QD)'	Amy McMahan (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:29
User entered empty.	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:31
User entered 'Oral (ORAL)'	Amy McMahan (b) (4)	20 Nov 2020 22:19:41
	(b) (4)	

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:33
User entered empty.	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:35
User entered 'UN UNK 2005'	Amy McMahan (b) (4)	20 Nov 2020 22:19:41
	(b) (4)	

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:36
User entered '0'	Amy McMahan (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:38
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:41
User entered empty.	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:08:53
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 22:19:41

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 22:24:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 22:24:03
Data point term sent to Coder	System	20 Nov 2020 22:22:55
Data point term sent to Coder	System	20 Nov 2020 22:21:54
User entered 'Metoprolol'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:11
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:26
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:22:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 22:22:10
User entered 'Hypertension' reason for change: Data Entry Error	Amy McMahan (b) (4)	20 Nov 2020 22:22:10
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:20:58
User entered empty.	Amy McMahan (b) (4)	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:23
User entered '25'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:28
User entered 'mg (mg)'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:30
User entered empty.	Amy McMahan (b) (4)	20 Nov 2020 22:20:58
	(b) (4)	

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:31
User entered 'once daily (QD)'	Amy McMahan (b) (4)	20 Nov 2020 22:20:58
	(b) (4)	

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:34
User entered empty.	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:36
User entered 'Oral (ORAL)'	Amy McMahan (b) (4)	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:38
User entered empty.	Amy McMahan (b) (4)	20 Nov 2020 22:20:58
	(b) (4)	

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:40
User entered 'UN UNK 2005'	Amy McMahan (b) (4)	20 Nov 2020 22:20:58
	(b) (4)	

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:42
User entered '0'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:43
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:45
User entered empty.	Amy McMahan (b) (4)	20 Nov 2020 22:20:58
	(b) (4)	

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:09:47
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 22:20:58

US3612010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 22:20:58

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'USA-US129-2020-MRNA-1273-P301000001'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

Serious

Audit	User	Time (GMT)
User closed query 'Source AE log states no. please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:10:17
Query 'Source AE log states no. please reconcile.' answered with 'updated' (Site from CRA).	Amy McMahan (b) (4)	20 Nov 2020 23:15:00
User opened query 'Source AE log states no. please reconcile.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:31:11
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:52
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Yes (Y)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Yes (Y)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Richard'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Rupp'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered '301 University Blvd'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Galveston'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'TX'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered '77555'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
User entered 'US'	System	09 Nov 2020 16:39:17

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 17:52:44
User entered '1'	System	09 Nov 2020 16:39:17

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'USA-US129-2020-MRNA-1273-P301000001'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

Serious

Audit	User	Time (GMT)
User closed query 'Source AE log states no. please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:10:17
Query 'Source AE log states no. please reconcile.' answered with 'updated' (Site from CRA).	Amy McMahan (b) (4)	20 Nov 2020 23:15:00
User opened query 'Source AE log states no. please reconcile.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:31:11
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:52
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Yes (Y)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Yes (Y)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Richard'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Rupp'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered '301 University Blvd'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Galveston'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'TX'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered '77555'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
User entered 'US'	System	09 Nov 2020 16:39:17

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 17:52:44
User entered '1'	System	09 Nov 2020 16:39:17

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
User entered '09/Nov/2020 11:39'	System	09 Nov 2020 16:39:17

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 16:39:17

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'USA-US129-2020-MRNA-1273-P301000001'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

Serious

Audit	User	Time (GMT)
User closed query 'Source AE log states no. please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:10:17
Query 'Source AE log states no. please reconcile.' answered with 'updated' (Site from CRA).	Amy McMahan (b) (4)	20 Nov 2020 23:15:00
User opened query 'Source AE log states no. please reconcile.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:31:11
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:52
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Yes (Y)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'No (N)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Yes (Y)'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Richard'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Rupp'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered '301 University Blvd'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'Galveston'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered 'TX'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 16:39:08
User entered '77555'	System	09 Nov 2020 16:38:47

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
User entered 'US'	System	09 Nov 2020 16:39:17

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 17:52:44
User entered '1'	System	09 Nov 2020 16:39:17

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:08:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
User entered '18/Nov/2020 17:52'	System	18 Nov 2020 17:52:44

US3612010

Folder: SAE USA-US129-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:08:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:30:43
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:52:44