

US3722034 (Prod: Keystone VitaLink Research - Greenville - PPDS)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:12:57

All time stamps listed in this document are displayed in GMT

US3722034

Form: Participant Creation

Generated On: 26 Nov 2020 11:12:57

[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 11:12:57

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	65
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 11:12:57

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:12:57

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:12:57

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:57

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:57

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:57

Condition	DIVERTICULITIS
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:57

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	2 NOV 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	NOV 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:57

Condition	GYNECOMASTIA, MALE
Start date (dd MMM yyyy)	UN FEB 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN OCT 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2017
Start Year (derived)	2017
Stop Month and Year (derived)	OCT 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:57

Condition	DEGENERATIVE DISC DISEASE WORSE AT L4-L5
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	2 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:38 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 12:38
Height (<i>xxx.x</i>)	143 cm
Weight (<i>xxx.x</i>)	233.8 lb
BMI (<i>xxx.x</i>)	51.96965 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 11:12:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐
	No ☒
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐
	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐
	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐
	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐
	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐
	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐
	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐
	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐
	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐
	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐
	No ☒
Other	Yes ☐
	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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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 11:12:57

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	2 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:57

What was the date of randomization? (dd MMM yyyy) 02 AUG 2020

What was the participant's randomization number? 184393

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:57

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 11:12:57

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)	2 AUG 2020
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 12:36
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 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 11:12:57

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)	2 AUG 2020
Time of assessment (00:00-23:59)	14:04 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 14:04
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 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 11:12:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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) 2 AUG 2020

What was the treatment time? (00:00-23:59) 13:34 (24 HR)

Treatment Date and Time (derived) 2 AUG 2020 13:34

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 11:12:57

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

2 AUG 2020

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

13:00 (24 HR)

Collection date and time (derived)

2 AUG 2020 13:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:57

Collection date (dd MMM yyyy)			2 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:01	2 AUG 2020 13:01
Nasopharyngeal Swab 2	Yes	13:01	2 AUG 2020 13:01

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

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 11:12:57

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 97.3 °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):

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 02 AUG 2020 14:12

PC Open Date & Time 02 AUG 2020 13:54

PC Close Date & Time 02 AUG 2020 16:24

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 17:24

PC Open Date & Time

02 AUG 2020 17:19

PC Close Date & Time

03 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

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

03 AUG 2020 13:56

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

04 AUG 2020 16:09

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

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

98.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

05 AUG 2020 16:18

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 13:03

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

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

98.2 °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

07 AUG 2020 12:35

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 15:59

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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

02 AUG 2020 14:13

PC Open Date & Time

02 AUG 2020 13:54

PC Close Date & Time

02 AUG 2020 16:24

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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 AUG 2020 17:24

PC Open Date & Time

02 AUG 2020 17:19

PC Close Date & Time

03 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

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

03 AUG 2020 13:56

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

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

04 AUG 2020 16:10

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

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

05 AUG 2020 16:18

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

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

06 AUG 2020 13:04

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

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

07 AUG 2020 12:35

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

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

08 AUG 2020 15:59

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 14:14
PC Open Date & Time	02 AUG 2020 13:54
PC Close Date & Time	02 AUG 2020 16:24

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 17:25
PC Open Date & Time	02 AUG 2020 17:19
PC Close Date & Time	03 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

Yes ☐	
PC Time stamp	03 AUG 2020 13:57
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

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

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

Yes ☐	
PC Time stamp	05 AUG 2020 16:19
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

Yes ☐	
PC Time stamp	06 AUG 2020 13:04
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

Yes ☐	
PC Time stamp	07 AUG 2020 12:36
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

Yes ☐	
PC Time stamp	08 AUG 2020 16:00
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3722034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

Was Contact Attempted?

Yes ☒

No ☐

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

09 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

Was Contact Attempted?

Yes ☒

No ☐

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

16 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	09:52 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 09:52
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 11:35
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3722034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	31 AUG 2020
What was the treatment time? (00:00-23:59)	11:05 (24 HR)
Treatment Date and Time (derived)	31 AUG 2020 11:05
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

US3722034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	31 AUG 2020
Collection time (<i>00:00-23:59</i>)	10:48 (24 HR)
Collection date and time (derived)	31 AUG 2020 10:48

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:57

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:11	31 AUG 2020 10:11
Nasopharyngeal Swab 2	Yes	10:11	31 AUG 2020 10:11

US3722034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 11:39

PC Open Date & Time

31 AUG 2020 11:25

PC Close Date & Time

31 AUG 2020 13:55

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 18:44

PC Open Date & Time

31 AUG 2020 14:50

PC Close Date & Time

01 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 17:12

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

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

98.8 °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

02 SEP 2020 12:42

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:13

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

04 SEP 2020 15:44

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 07:42

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 16:46

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 11:39

PC Open Date & Time

31 AUG 2020 11:25

PC Close Date & Time

31 AUG 2020 13:55

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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

31 AUG 2020 18:45

PC Open Date & Time

31 AUG 2020 14:50

PC Close Date & Time

01 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 17:13

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

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 SEP 2020 12:43

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 14:13

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

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

04 SEP 2020 15:44

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

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 07:42

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

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 SEP 2020 16:47

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 11:40
PC Open Date & Time	31 AUG 2020 11:25
PC Close Date & Time	31 AUG 2020 13:55

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 18:45
PC Open Date & Time	31 AUG 2020 14:50
PC Close Date & Time	01 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

Yes ☐	
PC Time stamp	01 SEP 2020 17:13
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

Yes ☐	
PC Time stamp	02 SEP 2020 12:43
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

Yes ☐	
PC Time stamp	03 SEP 2020 14:14
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

Yes ☐	
PC Time stamp	04 SEP 2020 15:45
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

Yes ☐	
PC Time stamp	06 SEP 2020 07:43
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

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 ☒

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

Yes ☐	
PC Time stamp	06 SEP 2020 16:47
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3722034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

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

US3722034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	5 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:01 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 14:01
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 OCT 2020

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

US3722034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 OCT 2020

Collection time (00:00-23:59)

14:35 (24 HR)

Collection date and time (derived)

5 OCT 2020 14:35

US3722034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

11 OCT 2020 13:46:21

Patient Cloud Open Date & Time

09 OCT 2020 00:01

Patient Cloud Close Date & Time

13 OCT 2020 23:59

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

20 OCT 2020 11:13:51

Patient Cloud Open Date & Time

16 OCT 2020 00:01

Patient Cloud Close Date & Time

20 OCT 2020 23:59

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	02 NOV 2020 09:16:16
Patient Cloud Open Date & Time	30 OCT 2020 00:01
Patient Cloud Close Date & Time	03 NOV 2020 23:59

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 11:24:38

Patient Cloud Open Date & Time

06 NOV 2020 00:01

Patient Cloud Close Date & Time

10 NOV 2020 23:59

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 10:58:48

Patient Cloud Open Date & Time

13 NOV 2020 00:01

Patient Cloud Close Date & Time

17 NOV 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

Date and time of submission

20 NOV 2020 10:13:17

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2020 00:01

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05 DEC 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2020 00:01

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12 DEC 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2021 00:01

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09 JAN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2021 00:01

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16 JAN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2021 00:01

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23 JAN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2021 00:01

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30 JAN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

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06 FEB 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

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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US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

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20 FEB 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

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US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

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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06 MAR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

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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US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

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20 MAR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2021 00:01

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03 APR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

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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10 APR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

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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US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

18 DEC 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

25 DEC 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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29 JAN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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12 FEB 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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19 FEB 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

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US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

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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US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

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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US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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Date and time of submission

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02 APR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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09 APR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

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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12 APR 2022 00:01

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16 APR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

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

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23 APR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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30 APR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2022 00:01

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02 JUL 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2022 00:01

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23 JUL 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2022 23:59

US3722034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

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

US3722034

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3722034

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:12:57

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3722034

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:12:57

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

AEID	USA-US083-2020-MRNA-1273-P30 1000001
Adverse event	METASTATIC CASTRATE SENSITIVE PROSTRATE CANCER WITH METASTASES
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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 ☐

v6.020 DTW (1102)

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US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

SUBJECT HAD MEDICAL
HISTORY OF PROSTATE
CANCER DIAGNOSED IN 2017.
SUBJECT REPORTED
WORSENING OF BACK PAIN
09SEP2020. SUBJECT
PRESENTED TODAY FOR DAY
57 AND REPORTED WORSENING
OF PROSTATE CANCER.
MEDICAL RECORD RELEASE
OBTAINED AND SITE WILL
UPDATE ONCE RECORDS ARE
RECEIVED AND REVIEWED.
COLONOSCOPY SHOWED
METAPLASTIC POLYPS
XRAY OF ABDOMEN SHOWED
MULTILEVEL LUMBAR
SPONDYLOSIS
CERVICAL XRAY SHOWED
POSSIBLE C4 FRACTURE OR
LYTIC CHANGES AS WELL AS
PLEURAL CHANGES.

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)	

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

AEID	
Adverse event	LOW IRON
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)	4 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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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US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

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) _____	

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

AEID	
Adverse event	CONSTIPATION
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	01 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

AEID	
Adverse event	WORSENING OF INSOMNIA
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)	1 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

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) _____	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

AEID	
Adverse event	LOW IRON
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)	1 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

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

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

AEID	
Adverse event	METAPLASTIC POLYPS IN COLON
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	01 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	1 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

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

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

AEID	
Adverse event	MULTILEVEL LUMBAR SPONDYLOSIS
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)	1 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	X-RAY OF THE ABDOMEN PERFORMED ON 01SEP2020 REVEALED MULTILEVEL LUMBAR SPONDYLOSIS
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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:12:57

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

Name of Medication	NAPROXEN
Prophylaxis	Yes ☐ No ☒
Indication	HIP PAIN
Dose per administration	220
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

Name of Medication	XTANDI
Prophylaxis	Yes ☐ No ☒
Indication	PROSTATE CANCER
Dose per administration	160
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication METASTATIC CASTRATE
SENSITIVE PROSTRATE
CANCER WITH METASTASES

Dose per administration 7.5-325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

Name of Medication	MELOXICAM
Prophylaxis	Yes ☐ No ☒
Indication	BACK PAIN RELATED TO METASTATIC CASTRATE SENSITIVE PROSTRATE CANCER WITH METASTASES
Dose per administration	15
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

Name of Medication	TRAMADOL
Prophylaxis	Yes ☒ No ☐
Indication	PAIN
Dose per administration	50
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

Name of Medication	FLOMAX
Prophylaxis	Yes ☐ No ☒
Indication	BENIGN PROSTATIC HYPERPLASIA
Dose per administration	0.4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

Name of Medication	MAGNESIUM CITRATE
Prophylaxis	Yes ☐ No ☒
Indication	CONSTIPATION/PAIN
Dose per administration	300
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

	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 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	UN SEP 2020	
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 ☒	

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:12:57

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:12:57

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
1 SEP 2020	COLONOSCOPY	Adverse Event	
1 SEP 2020	X-RAY OF THE ABDOMEN	Adverse Event	
3 SEP 2020	CERVICAL XRAY	Adverse Event	

US3722034

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:12:57

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

US3722034

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:12:57

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 ☐

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

SAEID	USA-US083-2020-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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:12:57

SAEID	USA-US083-2020-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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/OCT/2020 13:41
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

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:12:57

SAEID	USA-US083-2020-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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	11/NOV/2020 21:11
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

US3722034 (Prod: Keystone VitaLink Research - Greenville - PPDS)

US3722034

Form: Participant Creation

Generated On: 26 Nov 2020 11:12:57

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3722034'	RWS_ENDPOINT ENDPOINT (b) (4) 	02 Aug 2020 16:24:06

US3722034

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:51:45

US3722034

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '02 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	02 Aug 2020 16:24:07

US3722034

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:51:45

US3722034

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	02 Aug 2020 17:51:45

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Aug 2020 16:24:07

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

[Age](#)

Audit	User	Time (GMT)
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	02 Aug 2020 17:52:55
User entered '65' reason for change: Data Entry Error	Amy Ford (b) (4)	02 Aug 2020 17:52:55
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	02 Aug 2020 17:52:35
User entered '62'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '65'	System	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

White

Audit	User	Time (GMT)
User entered '1'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

Unknown

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:57

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:57

[Protocol Version](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 19:52:14
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'completed' (Site from DM).	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:29:30
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:29:26
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:56:40
User entered 'Amendment 5 (5)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:57

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:57

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:57

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Aug 2020 16:24:07

US3722034

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:57

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:12:57

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:32:46

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:57

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 16:34:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 16:34:01
Data point term sent to Coder	System	05 Aug 2020 16:33:38
User entered 'Prostate cancer'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2017'	System	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:57

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the laterality of HIP PAIN (Left, Right or Bilateral). Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:32:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 20:14:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 20:14:26
Query 'Per DM CLR: Please specify the laterality of HIP PAIN (Left, Right or Bilateral). Review and update Med History eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Amy Ford (b) (4)	05 Oct 2020 20:13:03
Data point term sent to Coder	System	05 Oct 2020 20:13:03
Coding entries removed.	Amy Ford (b) (4)	05 Oct 2020 20:12:44
User entered 'BILATERAL HIP PAIN' reason for change: Data Entry Error	Amy Ford (b) (4)	05 Oct 2020 20:12:44
User opened query 'Per DM CLR: Please specify the laterality of HIP PAIN (Left, Right or Bilateral). Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:25:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 02:01:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 02:01:39
Data point term sent to Coder	System	10 Aug 2020 02:00:42
User entered 'HIP PAIN'	Amy Ford (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'UN Jul 2020'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:57

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:02:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:02:43
Data point term sent to Coder	System	10 Nov 2020 22:01:49
User entered 'Diverticulitis'	Amy Ford (b) (4)	10 Nov 2020 22:00:57
	(b) (4)	

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'UN Jun 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:57

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:24:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:24:42
Data point term sent to Coder	System	10 Nov 2020 22:23:24
User entered 'INSOMNIA'	Amy Ford (b) (4)	10 Nov 2020 22:22:59
	(b) (4)	

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'UN Jul 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2 Nov 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Nov 2020'	System	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:57

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast disorders NEC, PT: Gynaecomastia, LLT: Gynaecomastia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:23:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:23:48
Data point term sent to Coder	System	11 Nov 2020 01:35:50
User entered 'Gynaecomastia, male'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'UN Feb 2017'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'UN Oct 2020'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Feb 2017'	System	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2017'	System	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:57

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Lumbar disc degeneration - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:18:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:18:45
Data point term sent to Coder	System	11 Nov 2020 01:35:50
User entered 'Degenerative Disc Disease worse at L4-L5'	Amy Ford (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2019'	System	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '12:38'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 12:38'	System	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '143' cm	Kayla Peay (b) (4)	05 Aug 2020 16:34:15
DataPoint set to visible.	(b) (4) System	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '233.8' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	07 Aug 2020 17:19:14
User entered '106' kg	Kayla Peay (b) (4)	05 Aug 2020 16:34:15
DataPoint set to visible.	System (b) (4)	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '51.96965'	System	16 Sep 2020 23:40:44
User entered '52.0'	System	07 Aug 2020 17:19:14
User entered '51.8'	System	05 Aug 2020 16:34:15
DataPoint set to visible.	System	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	05 Aug 2020 16:34:15
DataPoint set to visible.	System	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:28
User entered '97.8' F	Kayla Peay (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:28
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:28
User entered '73'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:28
User entered '17'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 13:43:28
User entered '134'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:28
User entered '85'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:21

US3722034

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	06 Sep 2020 14:07:40
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		31 Aug 2020 15:17:10
User entered '2 Aug 2020'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:21

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '1'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:57

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:58

US3722034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:58

US3722034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:55:58

US3722034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	02 Aug 2020 17:55:58

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '02 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	02 Aug 2020 17:29:05

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:57

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:40:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:40:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Aug 2020 17:29:05
User entered '184393' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Aug 2020 17:29:05

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	02 Aug 2020 17:29:05

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:57

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)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:57:35

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:57:35

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:57:35

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:57:35

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:57

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:57:35

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:57

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '143' cm reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:57

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '233.8' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:57

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '143' cm reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:57

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '233.8' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered 'No (N)'	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '12:36' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 12:36'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '17' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '85' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:57

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '143' cm reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:57

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '233.8' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered 'No (N)'	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 12:16:13
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 13:30:19
User entered '14:04' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 14:04'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '17' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '136' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '84' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:28:24
User entered 'No (N)'	Kayla Peay (b) (4)	05 Aug 2020 16:34:54

US3722034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:47
User entered '2 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:28:24
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:54

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '13:34'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 13:34'	System	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:13

US3722034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:13

US3722034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:00'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:13

US3722034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 13:00'	System	05 Aug 2020 16:35:13

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Aug 2020'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:57

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:01'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 13:01'	System	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:57

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:01'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '2 Aug 2020 13:01'	System	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:38

US3722034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 16:35:38

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:11:59', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	System	02 Aug 2020 18:13:01
User entered 'Yes (Y)'	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:12:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	System	02 Aug 2020 18:13:01
User entered '97.3'	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:12:27', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	System	02 Aug 2020 18:13:01
User entered 'Yes (Y)'	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:12:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	System	02 Aug 2020 18:13:01
User entered '0'	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 06:31:14
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONFIRM' (Site from System).	Amy Ford (b) (4)	09 Aug 2020 18:32:17
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	02 Aug 2020 18:13:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:12:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	System	02 Aug 2020 18:13:01
User entered '1'	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:12:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	System	02 Aug 2020 18:13:01
User entered '02 Aug 2020 14:12'	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 13:54'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 16:24'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:23:37', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e8454058-6690-4445-a016-7597ed78117d'	System	02 Aug 2020 21:24:06
User entered 'Yes (Y)'	System	02 Aug 2020 21:24:06

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:23:47', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e8454058-6690-4445-a016-7597ed78117d'	System	02 Aug 2020 21:24:06
User entered '98.2'	System	02 Aug 2020 21:24:06

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:23:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e8454058-6690-4445-a016-7597ed78117d'	System	02 Aug 2020 21:24:06
User entered 'No (N)'	System	02 Aug 2020 21:24:06

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:02', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e8454058-6690-4445-a016-7597ed78117d'	System	02 Aug 2020 21:24:06
User entered '02 Aug 2020 17:24'	System	02 Aug 2020 21:24:06

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 17:19'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 2'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:55:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '77317f7b-836e-40df-85e7-b885590fe334'	System	03 Aug 2020 17:56:08
User entered 'Yes (Y)'	System	03 Aug 2020 17:56:08

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:55:52', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '77317f7b-836e-40df-85e7-b885590fe334'	System	03 Aug 2020 17:56:08
User entered '98.2'	System	03 Aug 2020 17:56:08

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:55:59', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '77317f7b-836e-40df-85e7-b885590fe334'	System	03 Aug 2020 17:56:08
User entered 'No (N)'	System	03 Aug 2020 17:56:08

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:05', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '77317f7b-836e-40df-85e7-b885590fe334'	System	03 Aug 2020 17:56:08
User entered '03 Aug 2020 13:56'	System	03 Aug 2020 17:56:08

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 3'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:09:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '55b649c3-ffd5-4f70-9a3a-c090509da029'	System	04 Aug 2020 20:09:58
User entered 'Yes (Y)'	System	04 Aug 2020 20:09:58

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:09:45', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '55b649c3-ffd5-4f70-9a3a-c090509da029'	System	04 Aug 2020 20:09:58
User entered '97.6'	System	04 Aug 2020 20:09:58

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:09:51', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '55b649c3-ffd5-4f70-9a3a-c090509da029'	System	04 Aug 2020 20:09:58
User entered 'No (N)'	System	04 Aug 2020 20:09:58

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:09:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '55b649c3-ffd5-4f70-9a3a-c090509da029'	System	04 Aug 2020 20:09:58
User entered '04 Aug 2020 16:09'	System	04 Aug 2020 20:09:58

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 4'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:17:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	System	05 Aug 2020 20:18:15
User entered 'Yes (Y)'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:17:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	System	05 Aug 2020 20:18:15
User entered '98.4'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:17:50', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	System	05 Aug 2020 20:18:15
User entered 'Yes (Y)'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONFIRM' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 06:35:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	Amy Ford (b) (4)	09 Aug 2020 18:32:52
User entered '1'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	System	05 Aug 2020 20:18:15
User entered '0'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	System	05 Aug 2020 20:18:15
User entered '05 Aug 2020 16:18'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 5'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:18', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '08e8ddad-5810-4489-8423-df4becf417aa'	System	06 Aug 2020 17:03:40
User entered 'Yes (Y)'	System	06 Aug 2020 17:03:40

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '08e8ddad-5810-4489-8423-df4becf417aa'	System	06 Aug 2020 17:03:40
User entered '97.8'	System	06 Aug 2020 17:03:40

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '08e8ddad-5810-4489-8423-df4becf417aa'	System	06 Aug 2020 17:03:40
User entered 'No (N)'	System	06 Aug 2020 17:03:40

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '08e8ddad-5810-4489-8423-df4becf417aa'	System	06 Aug 2020 17:03:40
User entered '06 Aug 2020 13:03'	System	06 Aug 2020 17:03:40

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 6'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:10', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e293da09-4293-4123-919c-08e36af3db79'	System	07 Aug 2020 16:35:35
User entered 'Yes (Y)'	System	07 Aug 2020 16:35:35

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:22', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e293da09-4293-4123-919c-08e36af3db79'	System	07 Aug 2020 16:35:35
User entered '98.2'	System	07 Aug 2020 16:35:35

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e293da09-4293-4123-919c-08e36af3db79'	System	07 Aug 2020 16:35:35
User entered 'No (N)'	System	07 Aug 2020 16:35:35

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:33', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e293da09-4293-4123-919c-08e36af3db79'	System	07 Aug 2020 16:35:35
User entered '07 Aug 2020 12:35'	System	07 Aug 2020 16:35:35

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 7'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:58:47', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f57579b0-d0b4-4e05-a910-113f6a6c55a0'	System	08 Aug 2020 19:59:12
User entered 'Yes (Y)'	System	08 Aug 2020 19:59:12

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:58:59', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f57579b0-d0b4-4e05-a910-113f6a6c55a0'	System	08 Aug 2020 19:59:12
User entered '98.0'	System	08 Aug 2020 19:59:12

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f57579b0-d0b4-4e05-a910-113f6a6c55a0'	System	08 Aug 2020 19:59:12
User entered 'No (N)'	System	08 Aug 2020 19:59:12

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f57579b0-d0b4-4e05-a910-113f6a6c55a0'	System	08 Aug 2020 19:59:12
User entered '08 Aug 2020 15:59'	System	08 Aug 2020 19:59:12

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-02T14:13:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3dd9a292-e94f-4443-9aaa-5d98a7fa7418'	System	02 Aug 2020 18:13:57
User entered 'None (1)'	System	02 Aug 2020 18:13:57

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:13:32', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3dd9a292-e94f-4443-9aaa-5d98a7fa7418'	System	02 Aug 2020 18:13:57
User entered 'No (N)'	System	02 Aug 2020 18:13:57

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:13:36', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3dd9a292-e94f-4443-9aaa-5d98a7fa7418'	System	02 Aug 2020 18:13:57
User entered 'No (N)'	System	02 Aug 2020 18:13:57

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-02T14:13:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3dd9a292-e94f-4443-9aaa-5d98a7fa7418'	System	02 Aug 2020 18:13:57
User entered 'None (1)'	System	02 Aug 2020 18:13:57

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:13:53', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3dd9a292-e94f-4443-9aaa-5d98a7fa7418'	System	02 Aug 2020 18:13:57
User entered '02 Aug 2020 14:13'	System	02 Aug 2020 18:13:57

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 13:54'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 16:24'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-02T17:24:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '425a0a6a-9edd-437b-adf3-eacf834b295b'	System	02 Aug 2020 21:24:50
User entered 'None (1)'	System	02 Aug 2020 21:24:50

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '425a0a6a-9edd-437b-adf3-eacf834b295b'	System	02 Aug 2020 21:24:50
User entered 'No (N)'	System	02 Aug 2020 21:24:50

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '425a0a6a-9edd-437b-adf3-eacf834b295b'	System	02 Aug 2020 21:24:50
User entered 'No (N)'	System	02 Aug 2020 21:24:50

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-02T17:24:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '425a0a6a-9edd-437b-adf3-eacf834b295b'	System	02 Aug 2020 21:24:50
User entered 'None (1)'	System	02 Aug 2020 21:24:50

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:48', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '425a0a6a-9edd-437b-adf3-eacf834b295b'	System	02 Aug 2020 21:24:50
User entered '02 Aug 2020 17:24'	System	02 Aug 2020 21:24:50

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 17:19'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 2'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-03T13:56:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4713b51f-8d8b-40fe-8be0-ac1fadb9f10b'	System	03 Aug 2020 17:56:37
User entered 'None (1)'	System	03 Aug 2020 17:56:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4713b51f-8d8b-40fe-8be0-ac1fadb9f10b'	System	03 Aug 2020 17:56:37
User entered 'No (N)'	System	03 Aug 2020 17:56:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4713b51f-8d8b-40fe-8be0-ac1fadb9f10b'	System	03 Aug 2020 17:56:37
User entered 'No (N)'	System	03 Aug 2020 17:56:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-03T13:56:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4713b51f-8d8b-40fe-8be0-ac1fadb9f10b'	System	03 Aug 2020 17:56:37
User entered 'None (1)'	System	03 Aug 2020 17:56:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4713b51f-8d8b-40fe-8be0-ac1fadb9f10b'	System	03 Aug 2020 17:56:37
User entered '03 Aug 2020 13:56'	System	03 Aug 2020 17:56:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 3'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-04T16:10:03', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '594f4b57-b845-4595-a93b-7924b3e61257'	System	04 Aug 2020 20:10:26
User entered 'None (1)'	System	04 Aug 2020 20:10:26

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:09', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '594f4b57-b845-4595-a93b-7924b3e61257'	System	04 Aug 2020 20:10:26
User entered 'No (N)'	System	04 Aug 2020 20:10:26

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:14', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '594f4b57-b845-4595-a93b-7924b3e61257'	System	04 Aug 2020 20:10:26
User entered 'No (N)'	System	04 Aug 2020 20:10:26

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-04T16:10:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '594f4b57-b845-4595-a93b-7924b3e61257'	System	04 Aug 2020 20:10:26
User entered 'None (1)'	System	04 Aug 2020 20:10:26

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '594f4b57-b845-4595-a93b-7924b3e61257'	System	04 Aug 2020 20:10:26
User entered '04 Aug 2020 16:10'	System	04 Aug 2020 20:10:26

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 4'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-05T16:18:18', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ce64e10f-a966-4832-892c-86f4e8242a6c'	System	05 Aug 2020 20:18:36
User entered 'None (1)'	System	05 Aug 2020 20:18:36

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:22', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ce64e10f-a966-4832-892c-86f4e8242a6c'	System	05 Aug 2020 20:18:36
User entered 'No (N)'	System	05 Aug 2020 20:18:36

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:27', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ce64e10f-a966-4832-892c-86f4e8242a6c'	System	05 Aug 2020 20:18:36
User entered 'No (N)'	System	05 Aug 2020 20:18:36

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-05T16:18:31', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ce64e10f-a966-4832-892c-86f4e8242a6c'	System	05 Aug 2020 20:18:36
User entered 'None (1)'	System	05 Aug 2020 20:18:36

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:36', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ce64e10f-a966-4832-892c-86f4e8242a6c'	System	05 Aug 2020 20:18:36
User entered '05 Aug 2020 16:18'	System	05 Aug 2020 20:18:36

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 5'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-06T13:03:45', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '46aebea0-582c-4152-9336-5df2f637ac03'	System	06 Aug 2020 17:04:05
User entered 'None (1)'	System	06 Aug 2020 17:04:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '46aebea0-582c-4152-9336-5df2f637ac03'	System	06 Aug 2020 17:04:05
User entered 'No (N)'	System	06 Aug 2020 17:04:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:53', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '46aebca0-582c-4152-9336-5df2f637ac03'	System	06 Aug 2020 17:04:05
User entered 'No (N)'	System	06 Aug 2020 17:04:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-06T13:03:57', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '46aebea0-582c-4152-9336-5df2f637ac03'	System	06 Aug 2020 17:04:05
User entered 'None (1)'	System	06 Aug 2020 17:04:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '46aebea0-582c-4152-9336-5df2f637ac03'	System	06 Aug 2020 17:04:05
User entered '06 Aug 2020 13:04'	System	06 Aug 2020 17:04:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 6'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-07T12:35:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'aebb0f16-0baf-4e30-a054-3e8732fdb6be'	System	07 Aug 2020 16:36:03
User entered 'None (1)'	System	07 Aug 2020 16:36:03

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'aebb0f16-0baf-4e30-a054-3e8732fdb6be'	System	07 Aug 2020 16:36:03
User entered 'No (N)'	System	07 Aug 2020 16:36:03

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:50', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'aebb0f16-0baf-4e30-a054-3e8732fdb6be'	System	07 Aug 2020 16:36:03
User entered 'No (N)'	System	07 Aug 2020 16:36:03

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-07T12:35:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'aebb0f16-0baf-4e30-a054-3e8732fdb6be'	System	07 Aug 2020 16:36:03
User entered 'None (1)'	System	07 Aug 2020 16:36:03

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'aebb0f16-0baf-4e30-a054-3e8732fdb6be'	System	07 Aug 2020 16:36:03
User entered '07 Aug 2020 12:35'	System	07 Aug 2020 16:36:03

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 7'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-08T15:59:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9e57960d-1894-4058-9288-6a686385dc42'	System	08 Aug 2020 19:59:37
User entered 'None (1)'	System	08 Aug 2020 19:59:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9e57960d-1894-4058-9288-6a686385dc42'	System	08 Aug 2020 19:59:37
User entered 'No (N)'	System	08 Aug 2020 19:59:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9e57960d-1894-4058-9288-6a686385dc42'	System	08 Aug 2020 19:59:37
User entered 'No (N)'	System	08 Aug 2020 19:59:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-08T15:59:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9e57960d-1894-4058-9288-6a686385dc42'	System	08 Aug 2020 19:59:37
User entered 'None (1)'	System	08 Aug 2020 19:59:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9e57960d-1894-4058-9288-6a686385dc42'	System	08 Aug 2020 19:59:37
User entered '08 Aug 2020 15:59'	System	08 Aug 2020 19:59:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:33', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-02T14:14:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'No (N)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:44', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered '02 Aug 2020 14:14'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 13:54'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 16:24'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:57', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'None (0)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'None (0)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'None (0)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'None (0)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'None (0)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'None (0)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-02T17:25:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'No (N)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered '02 Aug 2020 17:25'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 17:19'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 2'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:45', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:53', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:57', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:57:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-03T13:57:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'No (N)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:57:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered '03 Aug 2020 13:57'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 3'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'None (0)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:41', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'None (0)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'Some interference with activity (2)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:11:02', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'None (0)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:11:07', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'None (0)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:11:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'None (0)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-04T16:11:27', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'No (N)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:11:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered '04 Aug 2020 16:11'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 4'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:44', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'None (0)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:55', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'None (0)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:19:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'None (0)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:19:09', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'None (0)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:19:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'None (0)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:19:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'None (0)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-05T16:19:26', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'No (N)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:19:31', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered '05 Aug 2020 16:19'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 5'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:37', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-06T13:04:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'No (N)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered '06 Aug 2020 13:04'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 6'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:05', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'None (0)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'None (0)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'None (0)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:15', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'None (0)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:18', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'None (0)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'None (0)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-07T12:36:31', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'No (N)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered '07 Aug 2020 12:36'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 7'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:50', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:53', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-08T16:00:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'No (N)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T16:00:03', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered '08 Aug 2020 16:00'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	10 Aug 2020 00:56:10
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	10 Aug 2020 00:55:55
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 00:55:55

US3722034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '09 Aug 2020' reason for change: Data Entry Error	Sara Poff (b) (4)	10 Nov 2020 22:20:01
User entered '9 Aug 2020' reason for change: Data Entry Error	Amy Ford (b) (4)	10 Aug 2020 00:56:10
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:55:55

US3722034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 00:55:55

US3722034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Aug 2020 00:55:55

US3722034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 00:56:18

US3722034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 00:56:18

US3722034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	16 Aug 2020 19:09:51

US3722034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Amy Ford (b) (4) (b) (4)	16 Aug 2020 19:09:51

US3722034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4) (b) (4)	16 Aug 2020 19:09:51

US3722034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	16 Aug 2020 19:09:51

US3722034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	16 Aug 2020 19:09:39

US3722034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:09:39

US3722034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	27 Aug 2020 12:50:59

US3722034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Kayla Peay (b) (4) (b) (4)	27 Aug 2020 12:50:59

US3722034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4) (b) (4)	27 Aug 2020 12:50:59

US3722034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	27 Aug 2020 12:50:59

US3722034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	27 Aug 2020 12:50:37

US3722034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 12:50:37

US3722034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	31 Aug 2020 15:17:10

US3722034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Sara Poff (b) (4) (b) (4)	31 Aug 2020 15:17:10

US3722034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Sara Poff (b) (4) (b) (4)	31 Aug 2020 15:17:10

US3722034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	31 Aug 2020 15:17:10

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '09:52'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 09:52'	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.1' F	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

Pulse (xxx)

Audit	User	Time (GMT)
User entered '70'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '20'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '113'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '77'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '11:35' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:35'	System	31 Aug 2020 18:58:45
User entered empty.	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '98.4' F reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '62' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 18:58:45
User entered empty.	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '17' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 18:58:45
User entered empty.	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '137' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 18:58:45
User entered empty.	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '86' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 18:58:45
User entered empty.	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:48

US3722034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:48

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Sara Poff (b) (4) (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Sara Poff (b) (4) (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Sara Poff (b) (4) (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '11:05'	Sara Poff (b) (4) (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:05'	System	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4) (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:00

US3722034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:00

US3722034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '10:48'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:00

US3722034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 10:48'	System	31 Aug 2020 15:21:00

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:57

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '10:11'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 10:11'	System	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:57

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '10:11'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 10:11'	System	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sara Poff (b) (4) (b) (4)	31 Aug 2020 15:17:47

US3722034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 15:17:47

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:38:39', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f1fa89a6-5cd0-4118-83a8-40303da8832b'	System	31 Aug 2020 15:47:49
User entered 'Yes (Y)'	System	31 Aug 2020 15:47:49

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:38:59', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f1fa89a6-5cd0-4118-83a8-40303da8832b'	System	31 Aug 2020 15:47:49
User entered '98.4'	System	31 Aug 2020 15:47:49

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f1fa89a6-5cd0-4118-83a8-40303da8832b'	System	31 Aug 2020 15:47:49
User entered 'No (N)'	System	31 Aug 2020 15:47:49

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f1fa89a6-5cd0-4118-83a8-40303da8832b'	System	31 Aug 2020 15:47:49
User entered '31 Aug 2020 11:39'	System	31 Aug 2020 15:47:49

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:25'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 13:55'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:44:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cf48a6b0-69ea-4d15-8c5a-34eaac6d7238'	System	31 Aug 2020 22:44:54
User entered 'Yes (Y)'	System	31 Aug 2020 22:44:54

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:44:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cf48a6b0-69ea-4d15-8c5a-34eaac6d7238'	System	31 Aug 2020 22:44:54
User entered '98.7'	System	31 Aug 2020 22:44:54

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:44:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cf48a6b0-69ea-4d15-8c5a-34eaac6d7238'	System	31 Aug 2020 22:44:54
User entered 'No (N)'	System	31 Aug 2020 22:44:54

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:44:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cf48a6b0-69ea-4d15-8c5a-34eaac6d7238'	System	31 Aug 2020 22:44:54
User entered '31 Aug 2020 18:44'	System	31 Aug 2020 22:44:54

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 14:50'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 2'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:12:15', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'lead28e5-9b4d-481b-a45b-4f8d638af202'	System	01 Sep 2020 21:12:39
User entered 'Yes (Y)'	System	01 Sep 2020 21:12:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:12:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'lead28e5-9b4d-481b-a45b-4f8d638af202'	System	01 Sep 2020 21:12:39
User entered '98.7'	System	01 Sep 2020 21:12:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:12:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'lead28e5-9b4d-481b-a45b-4f8d638af202'	System	01 Sep 2020 21:12:39
User entered 'No (N)'	System	01 Sep 2020 21:12:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:12:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'lead28e5-9b4d-481b-a45b-4f8d638af202'	System	01 Sep 2020 21:12:39
User entered '01 Sep 2020 17:12'	System	01 Sep 2020 21:12:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 3'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:41:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3149c421-e814-46fa-8029-53037ef37375'	System	02 Sep 2020 16:42:25
User entered 'Yes (Y)'	System	02 Sep 2020 16:42:25

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:42:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3149c421-e814-46fa-8029-53037ef37375'	System	02 Sep 2020 16:42:25
User entered '98.8'	System	02 Sep 2020 16:42:25

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:42:18', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3149c421-e814-46fa-8029-53037ef37375'	System	02 Sep 2020 16:42:25
User entered 'No (N)'	System	02 Sep 2020 16:42:25

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:42:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3149c421-e814-46fa-8029-53037ef37375'	System	02 Sep 2020 16:42:25
User entered '02 Sep 2020 12:42'	System	02 Sep 2020 16:42:25

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 4'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39a25c4f-9480-42c2-b54a-d283c8f6854c'	System	03 Sep 2020 18:13:27
User entered 'Yes (Y)'	System	03 Sep 2020 18:13:27

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:09', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39a25c4f-9480-42c2-b54a-d283c8f6854c'	System	03 Sep 2020 18:13:27
User entered '96.6'	System	03 Sep 2020 18:13:27

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39a25c4f-9480-42c2-b54a-d283c8f6854c'	System	03 Sep 2020 18:13:27
User entered 'No (N)'	System	03 Sep 2020 18:13:27

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39a25c4f-9480-42c2-b54a-d283c8f6854c'	System	03 Sep 2020 18:13:27
User entered '03 Sep 2020 14:13'	System	03 Sep 2020 18:13:27

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 5'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:43:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3ee7e733-886e-444d-aac8-3c1b55b54e95'	System	04 Sep 2020 19:44:20
User entered 'Yes (Y)'	System	04 Sep 2020 19:44:20

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3ee7e733-886e-444d-aac8-3c1b55b54e95'	System	04 Sep 2020 19:44:20
User entered '97.6'	System	04 Sep 2020 19:44:20

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:07', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3ee7e733-886e-444d-aac8-3c1b55b54e95'	System	04 Sep 2020 19:44:20
User entered 'No (N)'	System	04 Sep 2020 19:44:20

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3ee7e733-886e-444d-aac8-3c1b55b54e95'	System	04 Sep 2020 19:44:20
User entered '04 Sep 2020 15:44'	System	04 Sep 2020 19:44:20

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 6'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:41:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '5408e36b-6548-4373-97f7-d2cdd9ef041c'	System	06 Sep 2020 11:42:17
User entered 'Yes (Y)'	System	06 Sep 2020 11:42:17

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:41:50', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '5408e36b-6548-4373-97f7-d2cdd9ef041c'	System	06 Sep 2020 11:42:17
User entered '97.6'	System	06 Sep 2020 11:42:17

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:03', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '5408e36b-6548-4373-97f7-d2cdd9ef041c'	System	06 Sep 2020 11:42:17
User entered 'No (N)'	System	06 Sep 2020 11:42:17

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:07', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '5408e36b-6548-4373-97f7-d2cdd9ef041c'	System	06 Sep 2020 11:42:17
User entered '06 Sep 2020 07:42'	System	06 Sep 2020 11:42:17

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 7'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:46:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6eb45fb-1eaf-4175-9e38-0df60cd8c526'	System	06 Sep 2020 20:47:03
User entered 'Yes (Y)'	System	06 Sep 2020 20:47:03

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:46:50', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6eb45fb-1eaf-4175-9e38-0df60cd8c526'	System	06 Sep 2020 20:47:03
User entered '97.6'	System	06 Sep 2020 20:47:03

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:46:55', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6eb45fb-1eaf-4175-9e38-0df60cd8c526'	System	06 Sep 2020 20:47:03
User entered 'No (N)'	System	06 Sep 2020 20:47:03

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:46:59', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6eb45fb-1eaf-4175-9e38-0df60cd8c526'	System	06 Sep 2020 20:47:03
User entered '06 Sep 2020 16:46'	System	06 Sep 2020 20:47:03

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-31T11:39:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '38d4be73-a0b8-4a2a-9f50-0053344ed9d6'	System	31 Aug 2020 15:48:00
User entered 'None (1)'	System	31 Aug 2020 15:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:33', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '38d4be73-a0b8-4a2a-9f50-0053344ed9d6'	System	31 Aug 2020 15:48:00
User entered 'No (N)'	System	31 Aug 2020 15:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '38d4be73-a0b8-4a2a-9f50-0053344ed9d6'	System	31 Aug 2020 15:48:00
User entered 'No (N)'	System	31 Aug 2020 15:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-31T11:39:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '38d4be73-a0b8-4a2a-9f50-0053344ed9d6'	System	31 Aug 2020 15:48:00
User entered 'None (1)'	System	31 Aug 2020 15:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '38d4be73-a0b8-4a2a-9f50-0053344ed9d6'	System	31 Aug 2020 15:48:00
User entered '31 Aug 2020 11:39'	System	31 Aug 2020 15:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:25'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 13:55'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-31T18:44:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9ca4eb62-e195-47e9-b15a-1da0fa2fc3a9'	System	31 Aug 2020 22:45:24
User entered 'None (1)'	System	31 Aug 2020 22:45:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9ca4eb62-e195-47e9-b15a-1da0fa2fc3a9'	System	31 Aug 2020 22:45:24
User entered 'No (N)'	System	31 Aug 2020 22:45:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:05', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9ca4eb62-e195-47e9-b15a-1da0fa2fc3a9'	System	31 Aug 2020 22:45:24
User entered 'No (N)'	System	31 Aug 2020 22:45:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-31T18:45:14', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9ca4eb62-e195-47e9-b15a-1da0fa2fc3a9'	System	31 Aug 2020 22:45:24
User entered 'None (1)'	System	31 Aug 2020 22:45:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9ca4eb62-e195-47e9-b15a-1da0fa2fc3a9'	System	31 Aug 2020 22:45:24
User entered '31 Aug 2020 18:45'	System	31 Aug 2020 22:45:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 14:50'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 2'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-01T17:12:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '7616512e-858d-4257-aed4-b4de746081b6'	System	01 Sep 2020 21:13:13
User entered 'None (1)'	System	01 Sep 2020 21:13:13

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:12:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '7616512e-858d-4257-aed4-b4de746081b6'	System	01 Sep 2020 21:13:13
User entered 'No (N)'	System	01 Sep 2020 21:13:13

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '7616512e-858d-4257-aed4-b4de746081b6'	System	01 Sep 2020 21:13:13
User entered 'No (N)'	System	01 Sep 2020 21:13:13

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-01T17:13:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '7616512e-858d-4257-aed4-b4de746081b6'	System	01 Sep 2020 21:13:13
User entered 'None (1)'	System	01 Sep 2020 21:13:13

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '7616512e-858d-4257-aed4-b4de746081b6'	System	01 Sep 2020 21:13:13
User entered '01 Sep 2020 17:13'	System	01 Sep 2020 21:13:13

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 3'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-02T12:42:31', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6591f35-d858-4998-aeca-2012739a50f0'	System	02 Sep 2020 16:43:12
User entered 'None (1)'	System	02 Sep 2020 16:43:12

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:42:39', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6591f35-d858-4998-aeca-2012739a50f0'	System	02 Sep 2020 16:43:12
User entered 'No (N)'	System	02 Sep 2020 16:43:12

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:42:44', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6591f35-d858-4998-aeca-2012739a50f0'	System	02 Sep 2020 16:43:12
User entered 'No (N)'	System	02 Sep 2020 16:43:12

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-02T12:43:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6591f35-d858-4998-aeca-2012739a50f0'	System	02 Sep 2020 16:43:12
User entered 'None (1)'	System	02 Sep 2020 16:43:12

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:09', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6591f35-d858-4998-aeca-2012739a50f0'	System	02 Sep 2020 16:43:12
User entered '02 Sep 2020 12:43'	System	02 Sep 2020 16:43:12

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 4'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-03T14:13:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '63ed841e-0c86-4883-aa4b-96097f1d2a77'	System	03 Sep 2020 18:13:49
User entered 'None (1)'	System	03 Sep 2020 18:13:49

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:27', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '63ed841e-0c86-4883-aa4b-96097f1d2a77'	System	03 Sep 2020 18:13:49
User entered 'No (N)'	System	03 Sep 2020 18:13:49

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '63ed841e-0c86-4883-aa4b-96097f1d2a77'	System	03 Sep 2020 18:13:49
User entered 'No (N)'	System	03 Sep 2020 18:13:49

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-03T14:13:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '63ed841e-0c86-4883-aa4b-96097f1d2a77'	System	03 Sep 2020 18:13:49
User entered 'None (1)'	System	03 Sep 2020 18:13:49

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:44', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '63ed841e-0c86-4883-aa4b-96097f1d2a77'	System	03 Sep 2020 18:13:49
User entered '03 Sep 2020 14:13'	System	03 Sep 2020 18:13:49

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 5'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-04T15:44:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'b3015244-ab7f-4c40-8b61-c2939e7bcb9e'	System	04 Sep 2020 19:44:42
User entered 'None (1)'	System	04 Sep 2020 19:44:42

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:27', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'b3015244-ab7f-4c40-8b61-c2939e7bcb9e'	System	04 Sep 2020 19:44:42
User entered 'No (N)'	System	04 Sep 2020 19:44:42

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'b3015244-ab7f-4c40-8b61-c2939e7bcb9e'	System	04 Sep 2020 19:44:42
User entered 'No (N)'	System	04 Sep 2020 19:44:42

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-04T15:44:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'b3015244-ab7f-4c40-8b61-c2939e7bcb9e'	System	04 Sep 2020 19:44:42
User entered 'None (1)'	System	04 Sep 2020 19:44:42

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'b3015244-ab7f-4c40-8b61-c2939e7bcb9e'	System	04 Sep 2020 19:44:42
User entered '04 Sep 2020 15:44'	System	04 Sep 2020 19:44:42

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 6'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-06T07:42:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4208b4ca-ad6c-49ea-bbe7-fd0715a9aaa4'	System	06 Sep 2020 11:42:38
User entered 'None (1)'	System	06 Sep 2020 11:42:38

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4208b4ca-ad6c-49ea-bbe7-fd0715a9aaa4'	System	06 Sep 2020 11:42:38
User entered 'No (N)'	System	06 Sep 2020 11:42:38

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4208b4ca-ad6c-49ea-bbe7-fd0715a9aaa4'	System	06 Sep 2020 11:42:38
User entered 'No (N)'	System	06 Sep 2020 11:42:38

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-06T07:42:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4208b4ca-ad6c-49ea-bbe7-fd0715a9aaa4'	System	06 Sep 2020 11:42:38
User entered 'None (1)'	System	06 Sep 2020 11:42:38

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:26', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4208b4ca-ad6c-49ea-bbe7-fd0715a9aaa4'	System	06 Sep 2020 11:42:38
User entered '06 Sep 2020 07:42'	System	06 Sep 2020 11:42:38

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 7'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-06T16:47:05', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c078a101-b924-4906-89f9-25654c41ef78'	System	06 Sep 2020 20:47:24
User entered 'None (1)'	System	06 Sep 2020 20:47:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c078a101-b924-4906-89f9-25654c41ef78'	System	06 Sep 2020 20:47:24
User entered 'No (N)'	System	06 Sep 2020 20:47:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c078a101-b924-4906-89f9-25654c41ef78'	System	06 Sep 2020 20:47:24
User entered 'No (N)'	System	06 Sep 2020 20:47:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-06T16:47:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c078a101-b924-4906-89f9-25654c41ef78'	System	06 Sep 2020 20:47:24
User entered 'None (1)'	System	06 Sep 2020 20:47:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c078a101-b924-4906-89f9-25654c41ef78'	System	06 Sep 2020 20:47:24
User entered '06 Sep 2020 16:47'	System	06 Sep 2020 20:47:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:03', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-31T11:40:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'No (N)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:26', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered '31 Aug 2020 11:40'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:25'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 13:55'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:26', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'None (0)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'None (0)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'None (0)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'None (0)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'None (0)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'None (0)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-08-31T18:45:51', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'No (N)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:55', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered '31 Aug 2020 18:45'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 14:50'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 2'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:14', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:26', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-01T17:13:37', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'No (N)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:41', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered '01 Sep 2020 17:13'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 3'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:15', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:22', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-02T12:43:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'No (N)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered '02 Sep 2020 12:43'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 4'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:51', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:14:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:14:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:14:09', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:14:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-03T14:14:24', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'No (N)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:14:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered '03 Sep 2020 14:14'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 5'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:48', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d'	System	04 Sep 2020 19:45:19
User entered 'None (0)'	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:51', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d'	System	04 Sep 2020 19:45:19
User entered 'None (0)'	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:55', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d'	System	04 Sep 2020 19:45:19
User entered 'None (0)'	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d'	System	04 Sep 2020 19:45:19
User entered 'None (0)'	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:45:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d'	System	04 Sep 2020 19:45:19
User entered 'None (0)'	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:45:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d'	System	04 Sep 2020 19:45:19
User entered 'None (0)'	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-04T15:45:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d'	System	04 Sep 2020 19:45:19
User entered 'No (N)'	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:45:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d'	System	04 Sep 2020 19:45:19
User entered '04 Sep 2020 15:45'	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 6'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:32', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered 'None (0)'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered 'None (0)'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:39', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered 'None (0)'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered 'None (0)'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered 'None (0)'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered 'None (0)'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-06T07:43:02', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered 'No (N)'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:43:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered '06 Sep 2020 07:43'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 7'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:24', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:39', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-09-06T16:47:53', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'No (N)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:57', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered '06 Sep 2020 16:47'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:12:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	16 Sep 2020 14:56:54

US3722034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Kayla Peay (b) (4) (b) (4)	16 Sep 2020 14:56:54

US3722034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4) (b) (4)	16 Sep 2020 14:56:54

US3722034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	16 Sep 2020 14:56:54

US3722034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	16 Sep 2020 14:56:57

US3722034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:56:57

US3722034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	22 Sep 2020 20:04:06

US3722034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Amy Ford (b) (4) (b) (4)	22 Sep 2020 20:04:06

US3722034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4) (b) (4)	22 Sep 2020 20:04:06

US3722034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	22 Sep 2020 20:04:06

US3722034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	22 Sep 2020 20:04:12

US3722034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:04:12

US3722034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	23 Sep 2020 12:12:39

US3722034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Kayla Peay (b) (4) (b) (4)	23 Sep 2020 12:12:39

US3722034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4) (b) (4)	23 Sep 2020 12:12:39

US3722034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	23 Sep 2020 12:12:39

US3722034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	23 Sep 2020 12:12:43

US3722034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:12:43

US3722034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:03:33

US3722034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '5 Oct 2020'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:03:33

US3722034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:03:33

US3722034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:57

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	05 Oct 2020 18:03:33

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '14:01'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '5 Oct 2020 14:01'	System	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

Pulse (xxx)

Audit	User	Time (GMT)
User entered '73'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '18'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '80'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:37:59

US3722034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:37:59

US3722034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:39:52

US3722034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '5 Oct 2020'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:39:52

US3722034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '14:35'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:39:52

US3722034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '5 Oct 2020 14:35'	System	05 Oct 2020 18:39:52

US3722034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Oct 2020 18:39:55

US3722034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 18:39:55

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 71'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-10-11T13:46:03', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bffa922e-8288-4363-a5fa-1a797e7f1c63'	System	11 Oct 2020 17:46:27
User entered 'No (N)'	System	11 Oct 2020 17:46:27

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

Have you been exposed to someone with 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 (8f005bd6459ce894)', Time: '2020-10-11T13:46:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bffa922e-8288-4363-a5fa-1a797e7f1c63'	System	11 Oct 2020 17:46:27
User entered 'No (N)'	System	11 Oct 2020 17:46:27

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-10-11T13:46:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bffa922e-8288-4363-a5fa-1a797e7f1c63'	System	11 Oct 2020 17:46:27
User entered '11 Oct 2020 13:46:21'	System	11 Oct 2020 17:46:27

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '09 Oct 2020 00:01'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '13 Oct 2020 23:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 78'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[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 (8f005bd6459ce894)', Time: '2020-10-20T11:13:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '42dcd55b-0c21-4b12-be04-37e50d630f26'	System	20 Oct 2020 15:13:55
User entered 'No (N)'	System	20 Oct 2020 15:13:55

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

Have you been exposed to someone with 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 (8f005bd6459ce894)', Time: '2020-10-20T11:13:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '42dcd55b-0c21-4b12-be04-37e50d630f26'	System	20 Oct 2020 15:13:55
User entered 'No (N)'	System	20 Oct 2020 15:13:55

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-10-20T11:13:51', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '42dcd55b-0c21-4b12-be04-37e50d630f26'	System	20 Oct 2020 15:13:55
User entered '20 Oct 2020 11:13:51'	System	20 Oct 2020 15:13:55

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '16 Oct 2020 00:01'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '20 Oct 2020 23:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 92'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-11-02T09:15:47', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '99542cb9-df43-494a-955d-c1453e11bcb6'	System	02 Nov 2020 14:16:19
User entered 'Yes (Y)'	System	02 Nov 2020 14:16:19

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

Have you been exposed to someone with 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 (8f005bd6459ce894)', Time: '2020-11-02T09:15:57', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '99542cb9-df43-494a-955d-c1453e11bcb6'	System	02 Nov 2020 14:16:19
User entered 'No (N)'	System	02 Nov 2020 14:16:19

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-02T09:16:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '99542cb9-df43-494a-955d-c1453e11bcb6'	System	02 Nov 2020 14:16:19
User entered 'No (N)'	System	02 Nov 2020 14:16:19

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-02T09:16:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '99542cb9-df43-494a-955d-c1453e11bcb6'	System	02 Nov 2020 14:16:19
User entered 'No (N)'	System	02 Nov 2020 14:16:19

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-02T09:16:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '99542cb9-df43-494a-955d-c1453e11bcb6'	System	02 Nov 2020 14:16:19
User entered '02 Nov 2020 09:16:16'	System	02 Nov 2020 14:16:19

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '30 Oct 2020 00:01'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '03 Nov 2020 23:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 99'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[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 (8f005bd6459ce894)', Time: '2020-11-09T11:24:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c832ec52-c90e-4b64-9329-2c618a37f594'	System	09 Nov 2020 16:24:44
User entered 'No (N)'	System	09 Nov 2020 16:24:44

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

Have you been exposed to someone with 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 (8f005bd6459ce894)', Time: '2020-11-09T11:24:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c832ec52-c90e-4b64-9329-2c618a37f594'	System	09 Nov 2020 16:24:44
User entered 'No (N)'	System	09 Nov 2020 16:24:44

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-09T11:24:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c832ec52-c90e-4b64-9329-2c618a37f594'	System	09 Nov 2020 16:24:44
User entered '09 Nov 2020 11:24:38'	System	09 Nov 2020 16:24:44

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '06 Nov 2020 00:01'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '10 Nov 2020 23:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 106'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[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 (8f005bd6459ce894)', Time: '2020-11-17T10:58:31', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '71409c8b-ec2f-449c-b3a1-9b15b0c4b34f'	System	17 Nov 2020 15:58:51
User entered 'No (N)'	System	17 Nov 2020 15:58:51

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

Have you been exposed to someone with 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 (8f005bd6459ce894)', Time: '2020-11-17T10:58:37', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '71409c8b-ec2f-449c-b3a1-9b15b0c4b34f'	System	17 Nov 2020 15:58:51
User entered 'No (N)'	System	17 Nov 2020 15:58:51

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-17T10:58:48', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '71409c8b-ec2f-449c-b3a1-9b15b0c4b34f'	System	17 Nov 2020 15:58:51
User entered '17 Nov 2020 10:58:48'	System	17 Nov 2020 15:58:51

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '13 Nov 2020 00:01'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '17 Nov 2020 23:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '29 Sep 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 Oct 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Oct 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 Oct 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Oct 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 Oct 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Oct 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 Oct 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Oct 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '31 Oct 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 Nov 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '07 Nov 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 Nov 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '14 Nov 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

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 (8f005bd6459ce894)', Time: '2020-11-20T10:13:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '80f821f3-d2b1-480f-8bad-3d47270594e5'	System	20 Nov 2020 15:13:18
User entered 'No (N)'	System	20 Nov 2020 15:13:18

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

Have you been exposed to someone with 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 (8f005bd6459ce894)', Time: '2020-11-20T10:13:05', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '80f821f3-d2b1-480f-8bad-3d47270594e5'	System	20 Nov 2020 15:13:18
User entered 'No (N)'	System	20 Nov 2020 15:13:18

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-20T10:13:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '80f821f3-d2b1-480f-8bad-3d47270594e5'	System	20 Nov 2020 15:13:18
User entered '20 Nov 2020 10:13:17'	System	20 Nov 2020 15:13:18

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Wilson (b) (4) (b) (4)	30 Oct 2020 14:43:33

US3722034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020'	Taylor Wilson (b) (4) (b) (4)	30 Oct 2020 14:43:33

US3722034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4) (b) (4)	30 Oct 2020 14:43:33

US3722034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Taylor Wilson (b) (4) (b) (4)	30 Oct 2020 14:43:33

US3722034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Wilson (b) (4) (b) (4)	30 Oct 2020 14:43:38

US3722034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 14:43:38

US3722034

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:12:57

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:52:06
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:14:25

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:40:30
User entered 'USA-US083-2020-mRNA-1273-P301000001'	System	06 Oct 2020 13:40:22
User entered 'New'	(b) (4), (b) (6)	06 Oct 2020 13:40:22

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer metastatic, LLT: Prostate cancer metastatic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:44:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:44:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:15:19
Data point term sent to Coder	System	10 Nov 2020 22:22:24
DataPoint Un-verified.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:21:40
Coding entries removed.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:21:40
User entered 'Metastatic Castrate Sensitive Prostrate Cancer with Metastases' reason for change: New Information	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:21:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 05:39:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 05:39:35
Data point term sent to Coder	System	05 Oct 2020 18:18:43
User entered 'WORSENING OF PROSTATE CANCER'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Please verify start date, as source "record 4" indicates start date of 21Sep20, however, source AE log indicates start date of 23Sep20. Please ensure all records are correct and match. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:13:53
Query 'Please verify start date, as source "record 4" indicates start date of 21Sep20, however, source AE log indicates start date of 23Sep20. Please ensure all records are correct and match. Thank you.' answered with 'This has been clarified and the correct date of 23SEP2020 has been added. EDC is correct. ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	10 Nov 2020 18:50:04
User opened query 'Please verify start date, as source "record 4" indicates start date of 21Sep20, however, source AE log indicates start date of 23Sep20. Please ensure all records are correct and match. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:13:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:12:30
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 16:12:28
Query 'Please verify start date, as source indicates 221Sep20. Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:12:25
User opened query 'Please verify start date, as source indicates 221Sep20. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:08:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '23 Sep 2020'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please keep query open until end date achieved.' answered with 'This will be on going for a very long time. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 22:38:30
User opened query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please keep query open until end date achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	20 Nov 2020 21:59:45
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	11 Nov 2020 21:09:12
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'THIS EVENT HAS NOT ENDED, THEREFORE IS STILL ONGOING' (Site from Safety).	Taylor Wilson (b) (4) (b) (4)	10 Nov 2020 21:25:24
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	10 Nov 2020 16:05:08
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	22 Oct 2020 17:11:02
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	22 Oct 2020 16:53:34
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'This is still a ongoing event. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	21 Oct 2020 21:18:52
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	14 Oct 2020 15:53:20
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '1'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
Query 'Per CDM: Please review Action taken with investigational product field. Per CCGs, Not Applicable is ONLY expected if Adverse event is prior to first dose/investigational product' canceled (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:04:33
User opened query 'Per CDM: Please review Action taken with investigational product field. Per CCGs, Not Applicable is ONLY expected if Adverse event is prior to first dose/investigational product' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:40:26
User entered 'Not Applicable (NOT APPLICABLE)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '1'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject will be handling this for a very long time ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 22:40:16
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	20 Nov 2020 22:00:07
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) (b) (4)	11 Nov 2020 21:09:18
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 'RESOLUTION IS NOT EXPECTED IN NEAR FUTURE AS SUBJECT IS STILL CONTINUING TREATMENT FOR CANCER ' (Site from Safety).	Taylor Wilson (b) (4) (b) (4)	10 Nov 2020 21:26:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	10 Nov 2020 16:05:08
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	22 Oct 2020 17:11:24
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) (b) (4)	22 Oct 2020 16:53:36
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 'Still a ongoing issue. Will update when resolved. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	21 Oct 2020 21:19:23

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Outcome](#)

Audit	User	Time (GMT)
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)	14 Oct 2020 15:53:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Ford (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if subject is undergoing radiation, chemo, and/or has a planned surgery.' answered with 'Subject is undergoing chemo' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 22:35:21
User opened query 'PV Query: Please confirm if subject is undergoing radiation, chemo, and/or has a planned surgery.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	20 Nov 2020 22:00:51
User closed query 'PV Query: Please provide results of diagnostic tests (i.e. bone scan, pelvic CT, etc) performed in evaluation of prostate cancer.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	11 Nov 2020 21:09:47
User closed query 'PV Query: Please provide PSA results prior to start of study medication and at the time subject presented with prostate cancer' (Site from Safety).	(b) (4), (b) (6) (b) (4)	11 Nov 2020 21:09:40
User closed query 'PV Query: Please provide histology and TNM stage of prostate cancer.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	11 Nov 2020 21:09:26
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) (b) (4)	11 Nov 2020 21:09:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	11 Nov 2020 00:15:42
Query 'PV Query: Please provide results of diagnostic tests (i.e. bone scan, pelvic CT, etc) performed in evaluation of prostate cancer.' answered with 'COMPLETED' (Site from Safety).	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:20:46
DataPoint Un-verified.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:20:37

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAD MEDICAL HISTORY OF PROSTATE CANCER DIAGNOSED IN 2017. SUBJECT REPORTED WORSENING OF BACK PAIN 09SEP2020. SUBJECT PRESENTED TODAY FOR DAY 57 AND REPORTED WORSENING OF PROSTATE CANCER. MEDICAL RECORD RELEASE OBTAINED AND SITE WILL UPDATE ONCE RECORDS ARE RECIVED AND REVIEWED. COLONOSCOPY SHOWED METAPLASTIC POLYPS XRAY OF ABDOMEN SHOWED MULTILEVEL LUMBAR SPONDYLOSIS CERVICAL XRAY SHOWED POSSIBLE C4 FRACTURE OR LYTIC CHANGES AS WELL AS PLEURAL CHANGES.' reason for change: Data Entry Error	Amy Ford (b) (4)	10 Nov 2020 22:20:37
Query 'PV Query: Please provide PSA results prior to start of study medication and at the time subject presented with prostate cancer' answered with 'all available information has been entered' (Site from Safety).	Amy Ford (b) (4)	10 Nov 2020 22:17:42
Query 'PV Query: Please provide histology and TNM stage of prostate cancer.' answered with 'all available information has been entered' (Site from Safety).	Amy Ford (b) (4)	10 Nov 2020 22:17:31
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 'all available information has been entered' (Site from Safety).	Amy Ford (b) (4)	10 Nov 2020 22:17:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User opened query 'PV Query: Please provide results of diagnostic tests (i.e. bone scan, pelvic CT, etc) performed in evaluation of prostate cancer.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:54:44
User opened query 'PV Query: Please provide PSA results prior to start of study medication and at the time subject presented with prostate cancer' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:54:18

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide histology and TNM stage of prostate cancer.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:54:01
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)	14 Oct 2020 15:53:46
User entered 'SUBJECT HAD MEDICAL HISTORY OF PROSTATE CANCER DIAGNOSED IN 2017. SUBJECT REPORTED WORSENING OF BACK PAIN 09SEP2020. SUBJECT PRESENTED TODAY FOR DAY 57 AND REPORTED WORSENING OF PROSTATE CANCER. MEDICAL RECORD RELEASE OBTAINED AND SITE WILL UPDATE ONCE RECORDS ARE RECIVED AND REVIEWED.'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Water, electrolyte and mineral investigations, HLT: Mineral and electrolyte analyses, PT: Blood iron decreased, LLT: Iron low - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:03:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:03:56
Data point term sent to Coder	System	10 Nov 2020 22:02:50
User entered 'low iron'	Amy Ford (b) (4)	10 Nov 2020 22:02:37
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[None](#)

Audit	User	Time (GMT)
User entered '1'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:12:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:19:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:19:41
Data point term sent to Coder	System	10 Nov 2020 22:03:56
User entered 'neck pain'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:30:38
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4)	10 Nov 2020 22:04:29
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Nov 2020 22:03:49
User entered empty.	System	10 Nov 2020 22:03:49
	Amy Ford (b) (4)	
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:30:41
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4)	10 Nov 2020 22:04:13
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Nov 2020 22:03:49
User entered empty.	System	10 Nov 2020 22:03:49
	Amy Ford (b) (4)	10 Nov 2020 22:03:49
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:04:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:04:19
User entered 'No (N)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:04:19
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:03:49
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[None](#)

Audit	User	Time (GMT)
User entered '1'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 22:04:19

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:12:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:06:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:06:54
Data point term sent to Coder	System	10 Nov 2020 22:06:01
User entered 'constipation'	Amy Ford (b) (4)	10 Nov 2020 22:05:59
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:30:57
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4)	10 Nov 2020 22:06:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Nov 2020 22:05:59
User entered empty.	System	10 Nov 2020 22:05:59
	Amy Ford (b) (4)	
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[None](#)

Audit	User	Time (GMT)
User entered '1'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:12:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia exacerbated - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 22:42:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 22:42:41
Data point term sent to Coder	System	10 Nov 2020 22:24:25
User entered 'WORSENING OF INSOMNIA'	Amy Ford (b) (4)	10 Nov 2020 22:24:04
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:24:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:24:43
User entered '1 Sep 2020' reason for change: Data Entry Error	Amy Ford (b) (4)	10 Nov 2020 22:24:43
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:24:04
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:31:04
Query 'Data is required. Please provide.' answered with 'UNKNOWN' (Site from System).	Amy Ford (b) (4)	10 Nov 2020 22:24:51
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Nov 2020 22:24:43
User entered empty.	System	10 Nov 2020 22:24:04
	Amy Ford (b) (4)	
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[None](#)

Audit	User	Time (GMT)
User entered '1'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:12:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Water, electrolyte and mineral investigations, HLT: Mineral and electrolyte analyses, PT: Blood iron decreased, LLT: Iron low - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:43:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:43:40
Data point term sent to Coder	System	10 Nov 2020 22:26:27
User entered 'LOW IRON'	Amy Ford (b) (4)	10 Nov 2020 22:25:47
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:31:11
Query 'Data is required. Please provide.' answered with 'UNKNOWN' (Site from System).	Amy Ford (b) (4)	10 Nov 2020 22:25:54
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Nov 2020 22:25:47
User entered empty.	System	10 Nov 2020 22:25:47
	Amy Ford (b) (4)	10 Nov 2020 22:25:47
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[None](#)

Audit	User	Time (GMT)
User entered '1'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:12:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 22:25:47

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:57:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:57:10
Data point term sent to Coder	System	19 Nov 2020 13:13:06
User closed query 'For coding purposes, please enter the location for METAPLASTIC POLYPS in order that the term may be coded accurately and to the appropriate body site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	System	19 Nov 2020 13:12:18
Query 'For coding purposes, please enter the location for METAPLASTIC POLYPS in order that the term may be coded accurately and to the appropriate body site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' answered with 'completed and updated ' (Site from System).	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:12:18
Data point term sent to Coder	System	19 Nov 2020 13:12:05
User entered 'METAPLASTIC POLYPS in colon' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:11:09
User opened query 'For coding purposes, please enter the location for METAPLASTIC POLYPS in order that the term may be coded accurately and to the appropriate body site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:46:34
Data point term sent to Coder	System	11 Nov 2020 01:21:38
User entered 'Metaplastic polyps'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:31:17
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4)	11 Nov 2020 01:21:36
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Nov 2020 01:21:27
User entered empty.	System	11 Nov 2020 01:21:27
	Amy Ford (b) (4)	11 Nov 2020 01:21:27
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:31:19
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4)	11 Nov 2020 01:21:42
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Nov 2020 01:21:27
User entered empty.	System	11 Nov 2020 01:21:27
	Amy Ford (b) (4)	11 Nov 2020 01:21:27
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[None](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Polyps removed during colonoscopy'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 11:12:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Lumbar spondylosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:01:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:01:37
Data point term sent to Coder	System	11 Nov 2020 01:24:42
User entered 'Multilevel lumbar spondylosis'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:31:26
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4)	11 Nov 2020 01:24:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Nov 2020 01:24:35
User entered empty.	System	11 Nov 2020 01:24:35
	Amy Ford (b) (4)	11 Nov 2020 01:24:35
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[None](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Narrative](#)

Audit	User	Time (GMT)
User entered 'x-ray of the abdomen performed on 01Sep2020 revealed multilevel lumbar spondylosis'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 11:12:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 01:24:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:12:57

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:20:13
User closed query 'Per ETRTR: Please confirm medication dosed for SAE Worsening of Prostate Cancer if new dose or medication was provided, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:52:45
Query 'Per ETRTR: Please confirm medication dosed for SAE Worsening of Prostate Cancer if new dose or medication was provided, thanks.' answered with 'records requested and site will update once receive' (Site from CRA).	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:34
User opened query 'Per ETRTR: Please confirm medication dosed for SAE Worsening of Prostate Cancer if new dose or medication was provided, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 17:03:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:00:43
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 20:18:58

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:49:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:49:13
Data point term sent to Coder	System	10 Aug 2020 02:02:43
User entered 'NAPROXEN'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'HIP PAIN'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '220'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'mg (mg)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'as needed (PRN)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Oral (ORAL)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 15:20:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'PER PROTOCOL THIS IS TO BE RECORDED' (Site from System).	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 02:02:01
User entered 'UN Jul 2020'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:14
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: ANTI-ANDROGENS, PRODUCT: ENZALUTAMIDE, PRODUCTSYNONYM: XTANDI - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:45:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:45:11
Data point term sent to Coder	System	12 Aug 2020 19:44:39
Coding entries removed.	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 19:44:07
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: ANTI-ANDROGENS, PRODUCT: ENZALUTAMIDE, PRODUCTSYNONYM: XTANDI - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:49
Data point term sent to Coder	System	10 Aug 2020 19:28:11
User entered 'xtandi'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:15
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:18
User entered 'prostate cancer' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	12 Aug 2020 19:44:07
User entered 'medical history'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:01:55
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:23
User entered '160'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:01:41
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:01:57
User entered empty.	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:01:58
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:00
User entered empty.	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:02
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:03
User entered empty.	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 06:42:32
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 19:27:55
User entered 'un UNK 2018'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:10
User entered '0'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:12
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:13
User entered empty.	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:17
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:10:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:10:43
Data point term sent to Coder Coding entries removed.	System Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:54:31 10 Nov 2020 21:53:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:25:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:25:50
Data point term sent to Coder Coding entries removed.	System Taylor Wilson (b) (4) (b) (4)	10 Nov 2020 21:24:42 10 Nov 2020 21:24:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:11:30

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	14 Oct 2020 15:11:30
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	14 Oct 2020 15:10:31
User entered 'Hydrocodone/Acetaminophen'	Amy Ford (b) (4)	14 Oct 2020 15:10:15
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:05
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:07
User entered 'Metastatic Castrate Sensitive Prostrate Cancer with Metastases' reason for change: Data Entry Error	Amy Ford (b) (4)	10 Nov 2020 21:53:50
User entered 'WORSENING OF PROSTATE CANCER' reason for change: Data Entry Error	Taylor Wilson (b) (4)	10 Nov 2020 21:24:34
User entered 'back pain'	Amy Ford (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:09
User entered '7.5-325'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:10
User entered 'mg (mg)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:12
User entered empty.	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:16
User entered 'as needed (PRN)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:18
User entered empty.	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:19
User entered 'Oral (ORAL)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:21
User entered empty.	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:32:54
DataPoint Un-verified.	Sara Poff (b) (4)	11 Nov 2020 01:00:14
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 01:00:14
DataPoint Verified.	Sara Poff (b) (4)	11 Nov 2020 00:41:22
User entered '21 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 00:41:22
	(b) (4)	
	Amy Ford (b) (4)	14 Oct 2020 15:10:15
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:27
User entered '0'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:29
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:30
User entered empty.	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:32
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:56:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:56:34
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:07
Data point term sent to Coder	System	10 Nov 2020 21:53:29
User entered 'Meloxicam'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Back Pain related to Metastatic Castrate Sensitive Prostrate Cancer with Metastases'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '15'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'mg (mg)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'once daily (QD)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Oral (ORAL)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '9 Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:56:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:56:49
Data point term sent to Coder	System	10 Nov 2020 21:55:36
User entered 'Tramadol'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'pain'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '50'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'mg (mg)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'as needed (PRN)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Oral (ORAL)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'UN Jun 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'UN Oct 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:58:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:58:41
Data point term sent to Coder	System	10 Nov 2020 21:57:38
User entered 'Flomax'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Benign prostatic hyperplasia'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0.4'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'mg (mg)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'once daily (QD)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Oral (ORAL)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'UN Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:59:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
Data point term sent to Coder	System	10 Nov 2020 21:58:43
User entered 'MAGNESIUM CITRATE'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'CONSTIPATION/PAIN'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '300'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'mL (mL)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'once daily (QD)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Oral (ORAL)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'UN Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'UN Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:12:57

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:42
User entered 'Yes (Y)' reason for change: New Information	Amy Ford (b) (4)	11 Nov 2020 01:26:59
User entered 'No (N)'	Kayla Peay (b) (4)	05 Aug 2020 20:19:03

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:12:57

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered '1 Sep 2020'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:27:34

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:12:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'COLONOSCOPY'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:27:34

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:12:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'Adverse Event (AE)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:27:34

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:12:57

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:27:34

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:12:57

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered '1 Sep 2020'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:28:04

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:12:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'X-RAY OF THE ABDOMEN'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:28:04

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:12:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'Adverse Event (AE)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:28:04

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:12:57

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:28:04

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:12:57

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered '3 Sep 2020'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:31:44

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:12:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'CERVICAL XRAY'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:31:44

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:12:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'Adverse Event (AE)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:31:44

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:12:57

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:31:44

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:12:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered '06/Oct/2020 13:41'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:12:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered '1'	(b) (4), (b) (6)	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:12:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '11/Nov/2020 21:11'	System	11 Nov 2020 21:11:03

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:12:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 21:11:03